IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IMPAX LABORATORIES, INC.,
ASTRAZENECA AB, and
ASTRAZENECA UK LIMITED,

Plaintiffs,

v.

LANNETT HOLDINGS, INC. and
LANNETT COMPANY, INC.,

Defendants.

C.A. No. 14-984-RGA
(Consolidated)

PRE-TRIAL ORDER EXHIBIT 1:
JOINT STATEMENT OF ADMITTED FACTS

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Pursuant to Local Rule 16.3(c)(3), the parties stipulate to the following facts. These stipulated facts require no proof at trial and will become part of the evidentiary record in this case.

I. THE PARTIES

1. Plaintiffs in this lawsuit are Impax Laboratories, Inc. ("Impax"), AstraZeneca AB, and AstraZeneca UK Limited. AstraZeneca AB and AstraZeneca UK Limited will be referred to collectively as "AstraZeneca." Impax and AstraZeneca sometimes will be referred to collectively as "Plaintiffs."

2. Impax is a Delaware corporation with its headquarters at 30831 Huntwood Avenue, Hayward, CA 94544.

3. AstraZeneca AB is a Swedish corporation having its principal place of business at Karlebyhus, Astraallén, Södertälje, SE-151 85, Sweden.

4. AstraZeneca UK Limited is an English corporation having its headquarters at 2 Kingdom Street, Paddington, London, W2 6BD, England.

5. Defendants in this lawsuit are Lannett Holdings, Inc. and Lannett Company, Inc.

6. Lannett Holdings, Inc. and Lannett Company, Inc. will be referred to collectively as Lannett.

7. Lannett Holdings, Inc. is a corporation organized and existing under the laws of the State of Delaware having its principal place of business at 103 Foulk Road, Suite 202, Wilmington, DE 19803.

8. Lannett Company, Inc. is a corporation organized and existing under the laws of the State of Delaware having its principal place of business at 13200 Townsend Road, Philadelphia, PA 19154.

9. Lannett Company, Inc. is the parent company of Lannett Holdings, Inc.

II. THE PATENTS-IN-SUIT

A. The ’237 Patent

10. On June 15, 2004, the United States Patent and Trademark Office (“USPTO”) issued the ’237 patent, titled “Pharmaceutical Formulations Containing Zolmitriptan.”

11. The ’237 patent identifies Alan Roy Dearn, Sarah Louise Williamson, Simon John Summers, and Trevor John Coomber as inventors.

12. The ’237 patent is based upon U.S. Patent Application No. 10/129,773 filed May 9. 2002.

13. U.S. Patent Application No. 10/129,773 is a national stage filing under 35 U.S.C. 371 of PCT application PCT/GB00/04528, which was filed November 28, 2000.

14. U.S. Patent Application No. 10/129,773 makes a claim of priority to Great Britain Application No. 9928578, which was filed December 3, 1999.

15. The ’237 patent is subject to a patent term extension of 0 days.

B. The ’767 Patent

16. On May 22, 2007, the United States Patent and Trademark Office (“USPTO”) issued the ’767 patent, titled “Pharmaceutical Formulations Containing Zolmitriptan.”

17. The ’767 patent identifies Alan Roy Dearn, Sarah Louise Williamson, John Simon Summers, and Trevor John Coomber as inventors.

18. The ’767 patent is based upon U.S. Patent Application No. 10/854,959, which was filed on May 27, 2004.

19. U.S. Patent Application No. 10/854,959 is identified as a continuation of U.S. Patent Application No. 10/129,773 (the ’237 patent).

20. U.S. Patent Application No. 10/854,959 makes a claim of priority to Great Britain Application No. 9928578, which was filed December 3, 1999, through its parent application U.S. Patent Application No. 10/129,773.

21. The ’767 patent is subject to a terminal disclaimer over the ’237 patent.

22. The ’767 patent is subject to a patent term extension of 0 days.

III. ASTRAZENECA’S NEW DRUG APPLICATION (“NDA”)

23. The FDA approved two dosage forms of Zomig NS containing either 2.5 mg or 5.0 mg of zolmitriptan.

IV. LANNETT’S ANDA

24. On or about November 13, 2013, Lannett submitted ANDA No. 206350 to the FDA seeking the approval to manufacture commercially and sell its proposed product (the “Proposed Product”).

25. On or about June 13, 2014, Lannett sent AstraZeneca a “Notice of Paragraph IV Certifications” pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95, which discloses that its ANDA No. 206350 contained Paragraph IV certifications for the patents listed in the Orange Book as of the time of the Notice (the ’237 and ’767 patents).

V. LANNETT'S PROPOSED PRODUCT

26. The Proposed Product includes a pharmaceutical formulation suitable for intranasal administration.

27. The Proposed Product contains zolmitriptan in some ratio of free base to citrate form. The parties dispute whether that ratio includes a non-zero amount of zolmitriptan free base.

28. The Proposed Product includes an acceptable carrier.

29. The Proposed Product includes a pharmaceutical formulation that is buffered.

30. The Proposed Product includes a pharmaceutical formulation that is buffered by a mixture of citric acid and disodium phosphate.

VI. CLAIM CONSTRUCTION

31. D.I. 64 provides the following table:

Claim Term	Construction
preambles	Limiting.
"zolmitriptan"	Compound having the chemical name (S)-4-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-2-oxazolidinone and chemical structure:
"buffer," "buffered," and "in a buffer"	Formulations or material(s) therein that resist change in pH on adding acid or alkali or on dilution with solvent.
"disodium phosphate"	Compounds containing the basic structure as depicted in Figure 2 below, including all forms thereof, including sodium hydrogen phosphate; disodium hydrogen orthophosphate; sodium phosphate dibasic; dibasic sodium phosphate; disodium phosphate dodecahydrate; disodium phosphate heptahydrate; disodium phosphate dihydrate; and anhydrous disodium phosphate.
"pH of the formulation is 5"	The pH is 5 +/- 0.04.

VII. CLAIMS OF THE PATENTS-IN-SUIT

A. The ’237 Patent

32. The claims of the ’237 patent are as follows:

Claim 1	A pharmaceutical formulation suitable for intranasal administration which comprises zolmitriptan and a pharmaceutically acceptable carrier wherein the pH of the formulation is in the range 4.5 to 5.5.
Claim 2	A pharmaceutical formulation according to claim **1** wherein the pH of the formulation is 5.
Claim 3	A pharmaceutical formulation according to claim **1** wherein the formulation is buffered.
Claim 4	A pharmaceutical formulation according to claim **2** wherein the formulation is buffered.
Claim 5	A pharmaceutical formulation according to claim **1** which is sterile.
Claim 6	A pharmaceutical formulation according to claim **2** which is sterile.
Claim 7	A pharmaceutical formulation according to claim **3** which is sterile.
Claim 8	A pharmaceutical formulation according to claim **4** which is sterile.
Claim 9	A pharmaceutical formulation suitable for intranasal administration which comprises zolmitriptan and a pharmaceutically acceptable carrier wherein the pH of the formulation is less than 7.0, wherein the formulation is buffered by a mixture of citric acid and disodium phosphate.
Claim 10	A pharmaceutical formulation according to claim **9** which is sterile.
Claim 11	A pharmaceutical formulation suitable for intranasal administration which comprises zolmitriptan and a pharmaceutically acceptable carrier wherein the pH of the formulation is in the range 4.5 to 5.5, wherein the formulation is buffered by a mixture of citric acid and disodium phosphate.
Claim 12	A pharmaceutical formulation according to claim **11** which is sterile.
Claim 13	An intranasal administration device containing a pharmaceutical formulation as defined in any one of claims **1**, **2**, **9** or **11**.
Claim 14	The intranasal administration device of claim **13**, wherein the pharmaceutical formulation is packaged to protect the formulation from light.
Claim 15	An aqueous solution of zolmitriptan in a buffer at a pH in the range of 4.5 to 5.5.
Claim 16	The aqueous solution of claim **15**, wherein the pH is 5.

(*See* ’237 patent at cols. 5–6.)

B. The ’767 Patent

33. The claims of the ’767 patent are as follows:

Claim 1	A pharmaceutical formulation suitable for intranasal administration which comprises zolmitriptan and a pharmaceutically acceptable carrier wherein the pH of the formulation is less than 6.0.
Claim 2	A pharmaceutical formulation according to claim **1** wherein the pH of the formulation is in the range 3.5 to 5.5.
Claim 3	A pharmaceutical formulation according to claim **1** wherein the formulation is buffered.
Claim 4	A pharmaceutical formulation according to claim **2** wherein the formulation is buffered.
Claim 5	A pharmaceutical formulation suitable for intranasal administration which comprises zolmitriptan and a pharmaceutically acceptable carrier wherein the pH of the formulation is less than 6.0, wherein the formulation is buffered by a mixture of citric acid and disodium phosphate.
Claim 6	A pharmaceutical formulation suitable for intranasal administration which comprises zolmitriptan and a pharmaceutically acceptable carrier wherein the pH of the formulation is in the range 3.5 to 5.5, wherein the formulation is buffered by a mixture of citric acid and disodium phosphate.
Claim 7	A pharmaceutical formulation according to claim **1** which is sterile.
Claim 8	A pharmaceutical formulation according to claim **2** which is sterile.
Claim 9	A pharmaceutical formulation according to claim **3** which is sterile.
Claim 10	A pharmaceutical formulation according to claim **4** which is sterile.
Claim 11	A pharmaceutical formulation according to claim **5** which is sterile.
Claim 12	A pharmaceutical formulation according to claim **6** which is sterile.
Claim 13	An intranasal administration device containing a pharmaceutical formulation as defined in any one of claims **1**, **2**, **6** or **7**.
Claim 14	An intranasal administration device containing a pharmaceutical formulation as defined in any one of claims **1** to **12** when packaged to provide protection from light.
Claim 15	An aqueous solution of zolmitriptan in a buffer at a pH of less than 6.0.
Claim 16	The aqueous solution of claim **15**, wherein the pH is in the range 3.5 to 5.5.

(*See* '767 patent at cols. 5–6.)

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PRE-TRIAL ORDER EXHIBIT 2:
PLAINTIFFS' STATEMENT OF FACTS

Pursuant to Local Rule 16.3(c)(4), Plaintiffs Impax Laboratories, Inc., AstraZeneca AB, and AstraZeneca UK Limited submit the following issues of fact that remain to be litigated. Plaintiffs' identification of the issues of fact that remain to be litigated is based upon its current understanding of the arguments Defendants Lannett Holdings, Inc. and Lannett Company, Inc. (collectively, "Lannett") are likely to make, based on the pleadings, discovery, and expert reports in the action to date. To the extent that Lannett introduces different or additional facts or alleged facts to meet its burden of proof, Plaintiffs reserve the right to contest such facts or alleged facts, and to present any and all rebuttal evidence in response. By including a fact herein, Plaintiffs do not assume the burden of proof or production with regard to that fact.

To the extent that Plaintiffs' statement of issues of law set forth in Exhibit 4 contains issues of fact, those issues are incorporated herein by reference. Likewise, should the Court determine that any issue identified in this Exhibit 2 as an issue of fact is more appropriately considered an issue of law, Plaintiffs incorporate such issues by reference into their Exhibit 4.

I. INFRINGEMENT

Plaintiffs submit that the following issues remain to be litigated at trial with respect to infringement:

1. What the qualifications and knowledge of a person of ordinary skill in the art pertinent to the claims of the '237 patent and '767 patent were at the time of the invention of the claims of those patents.

2. Whether Plaintiffs have shown that Lannett's proposed product—a generic form of Plaintiffs' Zomig NS product and the subject of Lannett's ANDA No. 206350 (the "Proposed Product")—infringes each of claims 1–16 of the '237 patent and each of claims 1–16 of the '767 patent literally.

3. Whether Plaintiffs have shown that the Proposed Product infringes each of claims 1–16 of the ’237 patent and each of claims 1–16 of the ’767 patent under the doctrine of equivalents.

II. VALIDITY

Plaintiffs submit that the following issues remain to be litigated at trial with respect to validity:

4. What the qualifications and knowledge of a person of ordinary skill in the art pertinent to the claims of the ’237 patent and ’767 patent were at the time of the invention of the claims of those patents.

5. What the scope and content of the prior art was as of the invention date of the claims of the ’237 and ’767 patents.

6. What the differences are between the claims of the ’237 and ’767 patents and the prior art, and whether such differences rise to a patentable distinction.

7. Whether Lannett can prove by clear and convincing evidence that the claims of the ’237 and ’767 patents are invalid as anticipated, pursuant to 35 U.S.C. § 102, because each limitation of every claim is found expressly or inherently and as arranged in the claim in a single prior art reference, and in particular one of the following references for the listed claims:

Chauveau

‘237 patent, claims 1–8, 13, 15, 16

‘767 patent, claims 1–4, 7–10, 13, 15, 16

Rudolf

‘237 patent, claims 9, 10, 13

Marquess

‘237 patent, claims 1, 3–15

‘767 patent, claims 1, 3–15

8. Whether Lannett can prove by clear and convincing evidence that each of the claims of the ’237 and ’767 patents is invalid as obvious, pursuant to 35 U.S.C. § 103, to a person of ordinary skill in the art at the time that the claimed invention was made, in view of the scope and content of the prior art, the differences between the invention and the prior art, and the level of ordinary skill in the relevant art at that time, in light of one or more of the following references as combined below:

Ground	Reference Combinations Asserted by Lannett
1	Chauveau *in view of* Harris
2	Marquess *in view of* Harris
3	Rudolf *in view of* Harris
4	Iyengar *in view of* Watts; and Harris
5	Iyengar *in view of* Watts; and Clark
6	Iyengar *in view of* Watts; Uda; and McIlvaine
7	Oxford *in view of* Clark; Harris; and Remington’s

Ground	Reference Combinations Asserted by Lannett
8	Craig *in view of* Johnson; Harris; and Remington's
9	Rudolf *in view of* Aikawa; and McIlvaine
10	Sumatriptan Nasal Spray *in view of* Benjamin; Carstensen; Chauveau; Diamond; Gowan; Jager; Johnson; Marquess; McIlvaine; Nagai; Odusote; Penkler; Remington; Robertson; Roche; Rudolf; and Ukai

9. Whether Plaintiffs have shown the existence of secondary considerations of nonobviousness with respect to the claims of the '237 and '767 patents sufficient to override any showing of *prima facie* obviousness by Lannett with respect to any one or more of the following indicia:

a. long-felt but unmet needs satisfied by the claimed inventions;

b. failures in the field to achieve the claimed inventions;

c. unexpected, surprising, and/or beneficial properties or results regarding the claimed inventions;

d. industry acclaim or praise by others regarding the claimed inventions;

e. prior teachings away from the claimed inventions;

f. skepticism by others regarding the claimed inventions;

g. copying by others of the claimed inventions;

h. commercial success and licensing of the claimed inventions; or

i. any other indicia of non-obviousness.

III. OTHER ISSUES

10. What the plain and ordinary meaning of the term "pharmaceutical formulation suitable for intranasal administration" would mean to a person of ordinary skill in the art.

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EXHIBIT 3

LANNETT'S STATEMENT OF THE ISSUES OF FACT THAT REMAIN TO BE LITIGATED

Lannett's identification of issues of fact to be litigated is based in part on Lannett's understanding of Plaintiffs' arguments regarding its positions regarding the noninfringement and invalidity issues, which is based on Plaintiffs' disclosures, responses to Lannett's interrogatories, and expert reports.

To the extent that Lannett's statement of issues of law set forth in Exhibit 5 contains issues of fact, those issues are incorporated herein by reference. Likewise, should the Court determine that any issue identified in this Exhibit 3 as an issue of fact is more appropriately considered an issue of law, Lannett incorporates such issue into its Exhibit 5. By including a fact herein, Lannett does not assume the burden of proof or production with regard to the facts that are Plaintiffs' burden to prove.

Lannett reserves the right to revise this statement in light of the Court's rulings, or as otherwise appropriate.

Lannett submits that the following issues of fact remain to be litigated:

I. NON-INFRINGEMENT

1. Whether Plaintiffs have shown by a preponderance of the evidence that the sale, offer for sale, manufacture, use, or importation in or into the United States of Lannett's generic zolmitripan product that is the subject of ANDA No. 206350 ("Lannett's generic product") will infringe claims 1-16 of the '237 Patent literally or under the doctrine of equivalents.
2. Whether Plaintiffs have shown by a preponderance of the evidence that the sale, offer for sale, manufacture, use, or importation in or into the United States of Lannett's generic product will infringe claims 1-16 of the '767 Patent literally or under the doctrine of equivalents.
3. Whether Plaintiffs have shown by a preponderance of the evidence that Lannett's generic product contains "a pharmaceutical formulation suitable for intranasal administration."
4. Whether Plaintiffs have shown by a preponderance of the evidence that Lannett's generic product contains zolmitriptan in the "free base" form, i.e., not charged or ionically bonded.
5. Whether Plaintiffs have shown by a preponderance of the evidence that Lannett's generic product contains "a pharmaceutically acceptable carrier."
6. Whether Plaintiffs have shown by a preponderance of the evidence that the pH of Lannett's generic product formulation falls within each of the ranges claimed in the '237 or '767 Patents.

7. Whether Plaintiffs have shown by a preponderance of the evidence that Lannett's generic product is supplied in "an intranasal administration device containing a pharmaceutical formulation."

II. LEVEL OF SKILL IN THE ART

1. The level of ordinary skill in the art pertinent to claims 1-16 of the '237 Patent and claims 1-16 of the '767 Patent—in particular, whether a person of ordinary skill in the art, at the time of invention, would have a Ph.D. in Pharmaceutics, Chemistry or a related field with 2-3 years of experience with pharmaceutical design, formulation and testing, including for administration by nasal delivery, and would have experience in the analytical characterization of drug formulations, including in vitro testing of drug formulations, including as it relates to formulation stability, or would at least have a Bachelors or Master's degree in Pharmacy, Chemistry or a related field with at least 5 years of experience with pharmaceutical design, formulation and/or testing, including design, formulation and testing of pharmaceuticals intended for delivery by nasal administration.

III. INVALIDITY

A. Anticipation

1. Whether claims 1-16 of the '237 Patent are invalid as anticipated by the prior art under 35 U.S.C. § 102.
2. Whether claims 1-16 of the '767 Patent are invalid as anticipated by the prior art under 35 U.S.C. § 102.

B. Obviousness

1. The scope and content of the prior art relating to claims 1-16 of the '237 Patent.

2. The scope and content of the prior art relating to claims 1-16 of the '767 Patent.

3. The differences, if any, between the prior art and the subject matter claimed in claims 1-16 of the '237 Patent.

4. The differences, if any, between the prior art and the subject matter claimed in claims 1-16 of the '767 Patent.

5. Whether Lannett has proven by clear and convincing evidence that the subject matter claimed in claims 1-16 of the '237 Patent would have been obvious to a person of ordinary skill in the art.

6. Whether Lannett has proven by clear and convincing evidence that the subject matter claimed in claims 1-16 of the '767 Patent would have been obvious to a person of ordinary skill in the art.

7. Whether there was a motivation to make the subject matter claimed in any or all of the asserted claims of the '237 or '767 patents, and whether there would have been a reasonable expectation of success in doing so.

8. Whether Plaintiffs have shown the existence of any of the secondary considerations that they have asserted support non-obviousness—namely, long-felt but unmet needs, failure of others, unexpected results, industry acclaim, teaching away, copying, commercial success, and licensing—and if so, whether any of those secondary considerations shows that the

subject matter of claims 1-16 of the '237 Patent and claims 1-16 of the '767 Patent would not have been obvious to a person of ordinary skill in the art.

9. Whether Plaintiffs have established the existence of a nexus between the patented features of Plaintiffs' commercial product, Zomig®, and any of the secondary considerations listed in issue no. 8, above.

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PRE-TRIAL ORDER EXHIBIT 4:
PLAINTIFFS' STATEMENT OF ISSUES OF LAW

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Statutes

Rules

Pursuant to Local Rule 16.3(c)(5), Plaintiffs Impax Laboratories, Inc., AstraZeneca AB, and AstraZeneca UK Limited (collectively "Plaintiffs") submit this statement of issues of law which remain to be litigated. Plaintiffs' statement is based upon its current understanding of the arguments Defendants Lannett Holdings, Inc. and Lannett Company, Inc. (collectively, "Lannett") are likely to make, based on the pleadings, discovery, and expert reports in the action to date. Plaintiffs reserve the right to modify or supplement the statement to the extent necessary to reflect any future rulings by the Court or for any other good cause. Plaintiffs further reserve the right to modify or supplement the statement to address any new issues that Lannett may raise. To the extent that this exhibit contains issues of fact, those issues are incorporated into Plaintiffs' Issues of Fact by reference. Likewise, should the Court determine that any issue identified in Plaintiffs' Issues of Fact is more appropriately considered an issue of law, Plaintiffs incorporate such issues by reference in this Exhibit.

I. INFRINGEMENT

A. Generally

1. Anyone who "without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefore, infringes the patent." 35 U.S.C.A. § 271(a). The patentee must demonstrate by a preponderance of the evidence that the accused product meets each and every limitation of the accused claims. *Catalina Lighting, Inc. v. Lamps Plus, Inc.*, 295 F.3d 1277, 1285 (Fed. Cir. 2002).

2. "Infringement occurs when a properly construed claim reads on the accused product." *Monsanto Co. v. Scruggs*, 459 F.3d 1328, 1334 (Fed. Cir. 2006), *cert. denied*, 127 S. Ct. 2062 (U.S. 2007). This necessarily means that the first step in determining whether a claim is

infringed requires properly construing the claim terms. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995), *aff'd,* 517 U.S. 370 (1996); *Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1376 (Fed. Cir. 2005) ("Courts determine patent infringement by construing the patent's claims and then applying that construction to the accused process or product."). Second, one must compare the accused products to the construed claims, and determine if there is "sufficient evidence to prove that the accused product or process contains, either literally or under the doctrine of equivalents, every limitation of the properly construed claim." *Seal-Flex, Inc. v. Athletic Track and Court Const.*, 172 F.3d 836, 842 (Fed. Cir. 1999) (affirming jury verdict finding literal infringement).

3. The fact that only "trace" amounts of a patented compound may be found in a defendant's product does not preclude a finding of infringement. *See Organic Seed Growers and Trade Ass'n v. Monsanto Co.*, 718 F.3d 1350 (Fed. Cir. 2013) (ultimately finding covenant not to sue covered inadvertent use of "trace amounts" of its seeds and dismissing DJ action, stating that "we rejected the proposition that patent claims should be construed to avoid reading on 'trace amounts' of a patented compound, even though that compound's self-replicating properties might 'place potential infringers in the untenable position of never knowing whether their product infringes because even a single undetectable [molecule] would infringe.'"); *SunTiger, Inc. v. Scientific Research Funding Group*, 189 F.3d 1327, 1336 (Fed. Cir. 1999) ("The district court's error lies in the fact that we have never required that a claim read on the entirety of an accused device in order to infringe. If a claim reads merely on a part of an accused device, that is enough for infringement"); *see SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1341 (Fed. Cir. 2005) (finding because the accused infringer's "PHC anhydrate tablets would contain trace

amounts of PHC hemihydrate"—the patentee's active ingredient—the "product . . . infringe[d] under this court's claim construction.").

4. Courts have additionally held that that "if the prior art infringes now, logically the prior art should have anticipated the claim before the filing of the [patent in suit]." *SmithKline*, 403 at 1341. Commonsensically, the opposite is true as well — that which would anticipate before, infringes now.

5. Finally, while the Court has already made clear its construction of the claims does not exclude ionic forms of zolmitriptan, in the event that there remains any question regarding the reading of the claim terms, the Federal Circuit has made clear that "[a] construction that excludes all of the embodiments of an invention is rarely, if ever, correct." *Nellcor Puritan Bennett, Inc. v. Masimo Corp.*, 402 F.3d 1364, 1368 (Fed. Cir. 2005).

B. Infringement through ANDA Applications

6. Under 35 U.S.C. § 271(e), it is an act of infringement to submit an Abbreviated New Drug Application for a drug which is claimed in a patent. The proper inquiry under § 271(e)(2)(A) is to compare the properly construed claim to "the product that is likely to be sold following ANDA approval." *Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1186 (Fed. Cir. 2014). If the ANDA release specification, which describes the product that is likely to be sold following ANDA approval, is within the scope of the claim, then the product will infringe. *See Sunovion Pharm. Inc. v. Teva Pharm. USA, Inc.*, 731 F.3d 1271, 1279-80 (Fed. Cir. 2013); *see also Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1311 (Fed. Cir. 2015) (holding that an ANDA product having a pH of 6.8 to 7.2 literally infringed claims requiring a pH of "about 7.3"). The product will also infringe if the release specification is broader in scope than the

claim. *Sunovion*, 731 F.3d at 1279–80. Indeed, the Federal Circuit has held that an ANDA specification controls the infringement inquiry:

> This determination is based on consideration of all the relevant evidence, including the ANDA filing, other materials submitted by the accused infringer to the FDA, and other evidence provided by the parties. Because drug manufacturers are bound by strict statutory provisions to sell only those products that comport with the ANDA's description of the drug, an ANDA specification defining a proposed generic drug in a manner that directly addresses the issue of infringement will control the infringement inquiry….The converse must be true as well: If an ANDA specification defines a property of a compound such that it must meet a limitation of an asserted claim, then there will almost never be a genuine dispute of material fact that the claim is infringed with respect to that limitation.

Abbott Laboratories v. TorPharm, Inc., 300 F.3d 1367, 1373 (Fed. Cir. 2002) (internal quotations omitted).

7. When filing an Abbreviated New Drug Application, the applicant must submit a certification (a "Paragraph IV certification") which states that "in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug… that such patent is invalid or ***will not be infringed*** by the manufacture, use, or sale of the new drug for which the application is submitted." 21 U.S.C. § 355(j)(2)(vii)(IV) (emphasis added). "[T]he filing of a paragraph IV certification is itself an act of infringement if the purpose of the ANDA submission is to obtain the FDA's approval to engage in the commercial manufacture, use, or sale of a patented drug before expiration of the drug patent." *Abbott Laboratories v. TorPharm, Inc.*, 503 F.3d 1372, 1378–79 (Fed. Cir. 2007). "The Paragraph IV certification is designed to create a statutory act of infringement, in order to enable adjudication of issues of patent validity and infringement in the absence of actual manufacture, sale, or use of the product[.]" *Glaxo Wellcome, Inc. v. Andrx Pharms., Inc.*, 344 F.3d 1226, 1228 (Fed. Cir. 2003).

C. Doctrine of Equivalents

8. Even if a product does not literally infringe the claims of a patent, the product may nevertheless be found to infringe under the doctrine of equivalents. "Under this doctrine, a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21, 29, (1997).

9. "The doctrine of equivalents is intended to permit the patentee to enforce the patent against substantially the same invention, recognizing the strong constraints of the patent claims as the statement of the statutory patent right. Thus the doctrine of equivalents is invoked to prevent a 'fraud on the patent,' when an accused infringer is 'stealing the benefit of the invention' by making insubstantial changes that avoid the literal scope of the claims." *EMI Group North Am., Inc. v. Intel Corp.*, 157 F.3d 887, 896 (Fed. Cir. 1998) (internal citations omitted). The doctrine of equivalents recognizes the inherent inability of language to capture all meanings and nuances of an invention; "if patents were always interpreted by their literal terms, their value would be greatly diminished….The scope of a patent is not limited to its literal terms but instead embraces all equivalents to the claims described." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 731–32 (2002); *see also Miles Labs., Inc. v. Shandon Inc.*, 997 F.2d 870, 876 (Fed. Cir. 1993) ("The doctrine of equivalents thus prevents the risk of injustice that may result from a limited focus on words alone.").

10. "What constitutes equivalency must be determined against the context of the patent, the prior art, and the particular circumstances of the case. Equivalence, in the patent law, is not the prisoner of a formula and is not an absolute to be considered in a

vacuum….Consideration must be given to the purpose for which an ingredient is used in a patent, the qualities it has when combined with the other ingredients, and the function which it is intended to perform." *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 609 (1950), *superseded on other grounds by statute,* 35 U.S.C. § 112.

11. "An element in the accused product is equivalent to a claim limitation if the differences between the two are 'insubstantial' to one of ordinary skill in the art." *Catalina Marketing International, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 813 (Fed. Cir. 2002). The analysis also takes into consideration "whether a person reasonably skilled in the art would have known of the interchangeability of an ingredient not contained in the patent with one that was." *Graver Tank*, 339 U.S. at 609; *Overhead Door Corp. v. Chamberlain Group, Inc*., 194 F.3d 1261, 1270 (Fed. Cir. 1999) ("[T]he Supreme Court has acknowledged that interchangeability can be one of the hallmarks of an equivalent.")

12. While it is not the sole test for the doctrine of equivalents, "[a]n accused device may infringe a claim under the doctrine of equivalents if it performs substantially the same overall function or work, in substantially the same way, to produce substantially the same overall result as the claimed invention." *Dolly, Inc. v. Spalding & Evenflo Co., Inc.*, 16 F.3d 394, 397 (Fed. Cir. 1994); *Crown Packaging Tech., Inc. v. Rexam Beverage Can Co.*, 559 F.3d 1308, 1312 (Fed. Cir. 2009). "Under the doctrine of equivalents,…[t]he 'substantially the same way' prong of the test may be met if an equivalent of a recited limitation has been substituted in the accused device." *Read Corp. v. Portec, Inc.*, 970 F.2d 816, 822 (Fed. Cir. 1992) *superseded on other grounds by Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995).

13. In the case of an ANDA applicant, the Federal Circuit has found that where one ingredient has been replaced with another which performs substantially the same function, in

substantially the same way, to achieve substantially the same result, the doctrine of equivalents applies and the claims may be infringed. *Intendis GMBH v. Glenmark Pharms. Inc., USA*, 822 F.3d 1355 (Fed. Cir. 2016). A court may rely on statements by an accused infringer in its ANDA application, which may be "fatal" to an applicant's subsequent argument that an ingredient does not perform the same function. *Id*. at 1361–1363 (confirming district court's admonition that an ANDA applicant "should not be permitted to liken their product to the claimed composition to support their bid for FDA approval, yet avoid the consequences of such a comparison for purposes of infringement," stating "We see no reason why a district court acting as a fact finder should ignore a party's representation to a federal regulatory body that is directly on point").

14. The Federal Circuit has recognized that the doctrine of equivalents may be inapplicable in certain instances, such as where prosecution history estoppel applies; however, the presumption of surrender may be rebutted where the patentee can demonstrate:

> (1) the alleged equivalent would have been unforeseeable at the time ... the narrowing amendment was made;
>
> (2) the rationale underlying the narrowing amendment bore no more than a tangential relation to the equivalent at issue; or
>
> (3) there was some other reason suggesting that the patentee could not reasonably have been expected to have described the alleged equivalent.

Honeywell Int'l Inc. v. Hamilton Sundstrand Corp., 370 F.3d 1131, 1140 (Fed. Cir. 2004) (quotations omitted); *see also Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 344 F.3d 1359, 1368 (Fed. Cir. 2003) (en banc).

15. Moreover, "prosecution history estoppel will not bar the doctrine of equivalents when the reason for the narrowing amendment was peripheral, or not directly relevant, to the alleged equivalent." *Regents of University of Cal. v. Dakocytomation Cal., Inc.*, 517 F.3d 1364,

1378 (Fed. Cir. 2008) (internal quotation omitted); *Regents of University of Cal. v. Dakocytomation Cal., Inc*., 517 F.3d 1364, 1378 (Fed. Cir. 2008).

16. Reliance on an equivalent may also be barred by the doctrine of ensnarement, which prevents application of an equivalent that would result in the claims encompassing the prior art. *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1322 (Fed. Cir. 2009). "A helpful first step in an ensnarement analysis is to construct a hypothetical claim that literally covers the accused device…. Next, the district court must assess the prior art introduced by the accused infringer and determine whether the patentee has carried its burden of persuading the court that the hypothetical claim is patentable over the prior art. … Ultimately, [i]f such a claim would be unpatentable under 35 U.S.C. §§ 102 or 103, then the patentee has overreached, and the accused device is noninfringing as a matter of law." *Id*. at 1324–25 (denying ensnarement defense).

17. A further bar on the application of the doctrine of equivalents is the disclosure-dedication doctrine, which holds that a "clear, precise disclosure" of an equivalent in the specification of a patent, which is not also claimed, may dedicate this equivalent to the public. *See PSC Computer Prods., Inc. v. Foxconn Intern., Inc.*, 355 F.3d 1353, 1358 (Fed. Cir. 2004). The rule, however, "does not mean that any generic reference in a written specification necessarily dedicates all members of that particular genus to the public. The disclosure must be of such specificity that one of ordinary skill in the art could identify the subject matter that had been disclosed and not claimed." *Id*. at 1360. Public policy dictates that "before unclaimed subject matter is deemed to have been dedicated to the public, that unclaimed subject matter must have been identified by the patentee *as an alternative* to a claim limitation." *Pfizer, Inc. v. Teva Pharms., USA Inc.*, 429 F.3d 1364 (Fed. Cir. 2005) (emphasis added); *see also SanDisk*

Corp. v. Kingston Tech. Co., Inc., 695 F.33d 1348, 1363-64 (Fed. Cir. 2012) ("Whether a person of ordinary skill ultimately could employ the disclosures of the patent to implement a purported equivalent does not amount to actually disclosing to one of ordinary skill that equivalent as an alternative to a claim limitation"); *HSM Portfolio LLC v. Elpida Memory Inc.*, --- F.Supp.3d ----, 2016 WL 561179, at *11 (D. Del. Feb. 11, 2016) (relying on *PSC* and finding no alternative disclosure where "[t]he cited passages of the specification are nothing more than brief descriptions of the specification's figures. All they show is that the patentee was aware of NAND and NOR gates.").

II. VALIDITY

18. A patent is presumed valid as set forth in 35 U.S.C. § 282:

> A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim . . . The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.

This means that "[s]ection 282 requires an invalidity defense to be proved by clear and convincing evidence." *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2240 (2011); *see also, e.g., Z4 Techs., Inc. v. Microsoft Corp.*, 507 F.3d 1340, 1352 (Fed. Cir. 2007); *Schumer v. Lab. Computer Sys., Inc.*, 308 F.3d 1304, 1315 (Fed. Cir. 2002); *Novartis Pharms. Corp. v. Par Pharm., Inc.*, 48 F.Supp.3d 733, 752-53 (D. Del. 2014) ("The presumption that all patents are valid is the starting point for any obviousness determination…Obviousness must be proven by clear and convincing evidence"); *see also Carella v. Starlight Archery and Pro Line Co.*, 804 F.2d 135, 138 (Fed. Cir. 1986) ("Facts establishing anticipation or underlying a determination of obviousness must be proven by clear and convincing evidence.").

19. "Clear and convincing evidence places in the fact finder "an abiding conviction that the truth of [the] factual contentions are highly probable." *Procter & Gamble Co. v. Teva Pharmaceuticals USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009) (quoting *Colorado v. New Mexico*, 467 U.S. 310, 316 (1984)); *Intel Corp. v. U.S. Int'l Trade Comm'n*, 946 F.2d 821, 830 (Fed. Cir. 1991). "This burden 'exists at every stage of the litigation.'" *Id*. (quoting *Canon Computer Sys., Inc. v. Nu–Kote Int'l, Inc*., 134 F.3d 1085, 1088 (Fed. Cir. 1998)).

20. "It is not necessary that the court hold a patent valid; it is only necessary that it hold that the patent challenger has failed to carry its burden." *Ajinomoto Co. v. Archer-Daniels-Midland Co*., 1996 WL 621830, at *5 (D. Del. Oct. 21, 1996) (citing *Jones v. Hardy*, 727 F.2d 1524, 1529 n.3 (Fed. Cir. 1984)), *aff'd*, 228 F.3d 1338 (Fed. Cir. 2000). Indeed, "where the challenger fails to identify any persuasive evidence of invalidity, the very existence of the patent satisfies the patentee's burden on the validity issue." *Canon Computer Sys., Inc*., 134 F.3d at 1088.

21. "[A]lthough the standard of proof does not depart from that of clear and convincing evidence, a party challenging validity shoulders an enhanced burden if the invalidity argument relies on the same prior art considered during examination by the [PTO]." *Creative Compounds, LLC v. Starmark Laboratories*, 651 F.3d 1303, 1313 (Fed. Cir. 2011) (internal quotation omitted); *see also Metabolite Labs., Inc. v. Laboratory Corp. of Am. Holdings*, 370 F.3d 1354, 1367–68 (Fed. Cir. 2004); *Hewlett Packard Co. v. Bausch & Lomb, Inc.*, 909 F.2d 1464, 1467 (Fed. Cir. 1990). In that situation, the party asserting invalidity "has the added burden of overcoming the deference that is due to a qualified government agency presumed to have properly done its job, which includes one or more examiners who are assumed to have some expertise in interpreting the references and to be familiar from their work with the level of skill

in the art and whose duty it is to issue only valid patents." *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1304 (Fed. Cir. 2008) (quoting *Am. Hoist & Derrick Co.*, 725 F.2d 1350, 1359 (Fed. Cir. 1984)).

22. "When determining the validity of the claims of a patent, each claim must be separately considered." *Rasco, Inc. v. Mirror Lite Co.*, 304 F.3d 1373, 1379 (Fed. Cir. 2002); *see also Ortho Pharm. Corp. v. Smith*, 959 F.2d 936, 942 (Fed. Cir. 1992). This includes the consideration of whether a prior art reference anticipates the claims of a patent. *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1370–71 (Fed. Cir. 2003). *Schumer v. Lab. Comp. Sys., Inc.*, 308 F.3d 1304, 1316–17 (Fed. Cir. 2002).

23. A piece of prior art can invalidate a claimed invention if the defendant proves that the prior art shows that the claimed invention was "known or used by others in the U.S. or otherwise patented or described in a printed publication before invention date of what is claimed." 35 U.S.C. § 102(a). The term "printed publication" means a publication accessible to the public interested in the relevant art; it is the burden of the challenger to show that the document was made accessible to persons exercising reasonable diligence. *In re Lister*, 583 F.3d 1307, 1311–14, 92 USPQ2d 1225 (Fed. Cir. 2009).

A. Anticipation

24. To anticipate, a prior art reference must clearly and unequivocally disclose the claimed invention or direct one of ordinary skill to the invention without need for picking, choosing or combining various disclosures not directly related by the reference's teachings. *In re Arkley*, 455 F.2d 586, 587–88 (C.C.P.A. 1972); 35 U.S.C. § 102; *Silicon Graphics, Inc. v. ATI Techs., Inc.*, 607 F.3d 784, 796–97 (Fed. Cir. 2010) ("To show that a patent claim is invalid as anticipated, the accused infringer must show by clear and convincing evidence that a single prior

art reference discloses each and every element of a claimed invention"). As with all other aspects of validity, Lannett bears the burden of proving anticipation of the patents-in-suit by clear and convincing evidence. *Schumer*, 308 F.3d at 1315-16.

25. It is also Lannett's burden to demonstrate that the prior art is enabling. *Matsushita Elec. Indus. Co., Ltd. v. Samsung Elecs. Co., Ltd.*, 2006 WL 1794768, at *5 (D.N.J. 2006) ("An accused infringer attempting to invalidate a patent by anticipation bears the burden of proving by clear and convincing evidence 'that the four corners of a single, prior art document describe every element of the claimed invention.' This burden includes the ability to show that the reference is enabling"). An anticipating reference must "enable one of ordinary skill in the art to make the invention without undue experimentation." *Bard Peripheral Vascular, Inc. v. W.L. Gore & Associates, Inc.*, 670 F.3d 1171, 1185 (Fed. Cir. 2012) (*vacated in part on other grounds*, 476 Fed.Appx. 747 (Fed. Cir. 2012)).

26. A reference that discloses all elements of the claimed invention only anticipates if that reference also discloses all claim elements as arranged in the claim. *NetMoneyJN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369–71 (Fed. Cir. 2008); *In re Donohue*, 766 F.2d 531, 534 (Fed. Cir. 1985); *SRI Int'l, Inc. v. Cisco Sys., Inc.*, --- F.Supp.3d ---, 2016 WL 1437655, *9 (D. Del. Apr. 11, 2016) (denying summary judgment of anticipation, and *sua sponte* granting summary judgment of no anticipation, where prior art reference failed to disclose "all the limitations arranged as in the asserted claims").

27. A reference that is missing a particular feature of a patent can be said to inherently anticipate that patent only if the missing feature is necessarily, or inherently, present. Inherency can only be established when "prior art *necessarily* functions in accordance with, or includes, the claimed limitations." *Betcher Indus., Inc. v. Bunzl USA, Inc.*, 661 F.3d 629, 639 (Fed. Cir. 2011)

(emphasis added, quotation omitted). "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Oelrich,* 666 F.2d 578, 581 (CCPA 1981) (quotation omitted).

28. However, the Federal Circuit has "made clear that anticipation does not permit an additional reference to supply a missing claim limitation." *Teleflex, Inc. v. Ficosa North America Corp*., 299 F.3d 1313, 1335 (Fed. Cir. 2002). Further, "to incorporate material by reference [into the allegedly anticipating reference], the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents." *Advanced Display Sys., Inc. v. Kent State Univ*., 212 F.3d 1272, 1282 (Fed. Cir. 2000); *SkinMedica, Inc. v. Histogen Inc.*, 727 F.3d 1187, 1207 (Fed. Cir. 2013).

29. Moreover, where the reference is ambiguous, it will not support an anticipation rejection. *In re Hughes*, 345 F.2d 184, 188 (C.C.P.A. 1965); *In re Turlay*, 304 F.2d 893, 899 (C.C.P.A. 1962) ("It is well established that an anticipation rejection cannot be predicated on an ambiguous reference."). References are ambiguous "[w]here they are so vague, involved, intricate and contradictory that experts disagree radically as to their meaning and, following the instructions given, construct devices differing in fundamental features, it is safe to reject such a document as an anticipation." *In re Turlay*, 49 C.C.P.A. at 1295.

30. Likewise, a reference which merely provides a laundry list of compounds does not provide an anticipatory teaching of that compound's use. *Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1572 (Fed. Cir. 1992) (finding a prior patent that "state[d] in a very general way that fiberglass can be used as a substrate," did not disclose the "range of mesh sizes and thickness parameters that encompassed the range of

measurements claimed"); *Sanofi-Synthelabo v. Apotex Inc.*, 488 F.Supp.2d 317, 329 (S.D.N.Y. 2006) (finding reference disclosing hundreds of thousands of compounds was not anticipatory where "the sheer number of compounds in the class covered by the '596 patent indicates that the patent did not point a scientist towards the bisulfate salt of the dextrorotatory enantiomer of PCR 4099."). "It is well established that the disclosure of a genus in the prior art is not necessarily a disclosure of every species that is a member of that genus…. There may be many species encompassed within a genus that are not disclosed by a mere disclosure of the genus." *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 999 (Fed. Cir. 2006); *In re Baird,* 16 F.3d 380, 382 (Fed. Cir. 1994); *OSRAM Sylvania, Inc. v. Am. Induction Techs., Inc.*, 701 F.3d 698, 705-06 (Fed. Cir. 2012).

B. Obviousness

31. 35 U.S.C. § 103 sets forth the statutory basis of obviousness:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The Supreme Court has elucidated the following framework for making an obviousness determination: under § 103, the scope and content of the prior art are to be determined, differences between the prior art and the claims at issue are to be ascertained, and the level of ordinary skill in the pertinent art resolved. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). "[O]bviousness is a matter of law based on findings of underlying fact." *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1085 (Fed. Cir. 2008), *cert. denied*, 130 S. Ct. 493 (2009).

32. "The determination of obviousness is made with respect to the subject matter as a whole, not separate pieces of the claim." *Sanofi*, 550 F.3d at 1086. A "patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR*, 550 U.S. at 418. "Inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *Id*. at 418–19.

1. Obviousness Determinations Proceed in Two Stages

33. A determination of obviousness or nonobviousness proceeds in two stages. First, the patent challenger — here, Lannett — must establish by clear and convincing evidence that the claimed invention would have been *prima facie* obvious. *Kaufman Co. v. Lantech, Inc.*, 807 F.2d 970, 974-75 (Fed. Cir. 1986). "A party seeking to invalidate a patent based on obviousness must demonstrate …that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success.'" *Procter & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009) (citation omitted); *see also Amgen Inc. v. F. Hoffman-La Roche, Ltd.*, 580 F.3d 1340, 1362 (Fed. Cir. 2009); *Bayer AG v. Dr. Reddy's Labs., Ltd.*, 518 F. Supp. 2d 617, 624-25 (D. Del. 2007); *Ortho-McNeil Pharm., Inc., v. Mylan Labs., Inc.*, 520 F.3d 1358, 1364 (Fed. Cir. 2008) (motivation to modify the prior art must be shown as a guaranty against improper hindsight analysis with respect to obviousness); *Pfizer Inc. v. Watson Pharms., Inc.*, 920 F.Supp.2d 552 (D. Del. 2013) (finding, in ANDA litigation, patent not invalid for obviousness where no reasonable expectation of success, and where secondary considerations existed). Failure to show *prima facie* obviousness means the claims are not invalid for

obviousness, ending the inquiry. *Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1345 (Fed. Cir. 2000).

34. Second, assuming the challenger sets forth clear and convincing evidence of *prima facie* obviousness, the patentee can come forward with evidence to demonstrate that the invention was not obvious. *Pfizer v. Teva Pharm. U.S.A., Inc.*, 882 F.Supp.2d 643, 665 (D. Del. 2012) ("even if the challenger is able to establish the *prima facie* case of obviousness, the patentee may rebut it with evidence of "some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected."). For example, evidence showing that the invention has an unexpected, superior property compared to the prior art can rebut a *prima facie* case. *Prima facie* obviousness may also be rebutted with objective indicia of non-obviousness ("secondary considerations") such as satisfaction of a long-felt need by the invention, public acclaim for the invention, copying of the invention, teaching way from the invention, failure of others to achieve the invention, commercial success, and skepticism for the invention. *See, e.g.*, *KSR*, 550 U.S. at 406 ("Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., may be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.") (quoting *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966)); *Smith v. Goodyear Dental Vulcanite Co.*, 93 U.S. 486, 495–96 (1876) ("considerations of long felt need, commercial success in patented invention displacing prior devices, recognition by experts that the invention was novel may … always be considered; and, when the other facts in the case leave the question in doubt, it is sufficient to turn the scale."); *Plantronics, Inc. v. Aliph, Inc.*, 724 F.3d 1343, 1355 (Fed. Cir. 2013) (reversing finding of obviousness because "'common sense' may not be so apparent in view of objective evidence of nonobviousness (*e.g.*, commercial success and copying)"); *In re*

Chupp, 816 F.2d 643, 646–47 (Fed. Cir. 1987) (reversing finding of obviousness based on unexpected results); *Monarch Knitting Mach. Corp. v. Sluzer Morat GmbH,* 139 F.3d 877, 885 (Fed. Cir. 1988) (finding skepticism a secondary consideration supporting nonobviousness); *KSR*, 550 U.S. at 416 (holding patented invention successfully combining elements despite teaching away in prior art nonobvious).

35. Moreover, even when the patentee comes forward with evidence of secondary considerations or unexpected results, the burden of proof that the claims were obvious in light of *all* of the evidence remains with the patent challenger, who must show clear and convincing evidence of obviousness. *See Hybritech Inc.*, 802 F.2d at 1375, 1383; *Ortho-McNeil Pharm., Inc. v. Mylan Laboratories, Inc.*, 348 F.Supp.2d 713, 749 (N.D.W. Va. 2004).

36. Once sufficient rebuttal evidence has been presented, "the *prima facie* case dissolves, and the decision is made on the entirety of the evidence." *In re Kumar*, 418 F.3d 1361, 1366 (Fed. Cir. 2005). In making its final determination, a court must consider all of the above-noted factors including secondary considerations. *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 663 (Fed. Cir. 2000). Evidence of secondary considerations, which "may often be the most probative and cogent evidence of non-obviousness in the record" (*Procter & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 998 (Fed. Cir. 2009) (internal quotations and citation omitted)), and which "may often establish that an invention appearing to have been obvious in light of the prior art was not" (*Crocs, Inc. v. Int'l Trade Comm'n,* 598 F.3d 1294, 1310 (Fed. Cir. 2010) (citing *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-39 (Fed. Cir. 1983))), "is to be considered as part of all the evidence, not just when the decisionmaker remains in doubt after reviewing the art." *Stratoflex,* 713 F.2d at 1538-39; *Lindemann Maschinenfabrik GMBH v. Am. Hoist and Derrick Co.*, 730 F.2d 1452, 221 U.S.P.Q. 481 (Fed. Cir. 1984) (finding district court

erred in not considering secondary considerations in initial obviousness determination, stating, "[t]he district court correctly stated that commercial success cannot by *itself* establish nonobviousness"); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1380, 1382-84 (Fed. Cir. 1986).

37. Courts have long recognized the unpredictability of medicinal chemistry. *See, e.g.*, *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1564 (Fed. Cir. 1996) ("It may be difficult to predict, however, whether a novel compound will exhibit pharmacological activity, even when the behavior of analogous compounds is known to those skilled in the art"); *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995) (referring to "the less predictable fields, such as chemistry, where minor changes in a product or process may yield substantially different results"); *In re Brana*, 51 F.3d 1560, 1567 (Fed. Cir. 1995) ("minor changes in chemical compounds can radically alter their effects on the human body"); *Ortho Pharm. Corp. v. Smith*, 959 F.2d 936, 943 (Fed. Cir. 1992) ("one could not predict the effect of small structural changes on the biological activity of steroid hormones"); *Sanofi*, 550 F.3d at 1086, 1090 (upholding district court's finding of nonobviousness based on the "unpredictable and unusual properties of [the chemical] and the therapeutic advantages thereby provided," and noting that by contrast *KSR* involved a "mechanical device made by combining known components to produce a combination having the properties of the known components."). "To the extent an art is unpredictable, as the chemical arts often are, *KSR*'s focus on these 'identified predictable solutions' may present a difficult hurdle because potential solutions are less likely to be genuinely predictable." *Eisai Co. v. Dr. Reddy's Labs., Ltd.*, 533 F.3d 1353, 1359 (Fed. Cir. 2008).

38. It is furthermore inappropriate in at least three situations to apply "common sense" in an obviousness analysis: "[f]irst, common sense is typically invoked to provide a

known motivation to combine, not to supply a missing claim limitation." *Arendi S.A.R.L. v. Apple Inc.*, --- F.3d ----, 2016 WL 4205964, at *4 (Fed. Cir. Aug. 10, 2016). Second, where common sense is used in supplying a missing claim limitation, it should only apply where the missing limitations is "unusually simple and the technology particularly straightforward. *Id*. at *5. "Third . . . common sense . . . cannot be used as a wholesale substitute for reasoned analysis and evidentiary support, especially when dealing with a limitation missing from the prior art references specified." *Id*. Finally, common sense cannot overcome "important" claim limitations without supporting evidence. *Id*. at *6.

a) The Person of Ordinary Skill in the Art

39. An invention is not patentable if it would have been obvious to a person having ordinary skill in the art at the time the invention was made. *Takeda Chem. Indus, Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1354-55 (Fed. Cir. 2007). "Factors that may be considered in determining the ordinary level of skill in the art include: 1) the types of problems encountered in the art; 2) the prior art solutions to those problems; 3) the rapidity with which innovations are made; 4) the sophistication of the technology; and 5) the educational level of active workers in the field." *Ruiz*, 234 F.3d at 666–67. "Not all such factors may be present in every case, and one or more of them may predominate." *Id*. at 667 (citation and internal quotation omitted).

40. An obviousness determination is therefore made "from the viewpoint of a person of ordinary skill [not the inventor] in the field of the invention." *IGT v. Bally Gaming Int'l, Inc*., 610 F. Supp. 2d 288, 329 (D. Del. 2009) (quoting *Arkie Lures, Inc. v. Gene Larew Tackle, Inc.*, 119 F.3d 953, 956 (Fed. Cir. 1997)). Evidence must be provided that "the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed

invention, would select the elements from the cited prior art references for combination in the manner claimed." *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998).

41. In determining the level of a person of skill in the art, the Court should consider "(1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field." *Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007) (finding "[t]he art involved in the ′741 patent is the creation of a compound to treat ear infections without damaging a patient's hearing" despite the fact that the patent was "drawn to a method for treating bacterial ear infections by topically administering the antibiotic ofloxacin into the ear"). The analysis should not be limited to merely what is primarily discussed or claimed in the invention, however, but should extend to all aspects discussed in the patent as a whole. *See, e.g.*, *AstraZeneca Pharms. LP v. Anchen Pharms., Inc.*, 2012 WL 1065458 (D.N.J. Mar. 29, 2012) (finding in a patent directed to "sustained release formulations of the antipsychotic compound quetiapine and a method for treating psychotic states by administering an effective amount of the claimed formulations," that a POSA was not limited to formulation chemists but also included clinicians, further stating that "at the relevant time the field of formulation science was complex and could be unpredictable. Also, there were many available formulation systems for a POSA to try who wished to create a sustained release formulation."); *Takeda Pharm. Co. v. Mylan Inc.*, 2014 WL 5862134 (N.D. Cal. Nov. 11, 2014) (considering not only the primary discussion of synthesis and characterization of crystalline dexlansoprazole and formulations of dosage forms, but also the fact that the patent "discuss[ed] aspects of clinical use").

b) The Challenger Cannot Use Hindsight or Rely on the Path of the Inventor

42. The obviousness analysis takes place at the time of the invention, and focuses on evidence existing before the time of the invention. *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d at 1364–65. Accordingly, an obviousness analysis "requires the analysis to examine 'the subject matter as a whole' to ascertain if it 'would have been obvious at the time the invention was made.'" *Id.* at 1364 (quoting 35 U.S.C. § 103(a)) (emphasis omitted).

43. The obviousness analysis must avoid using the teachings of the patent-in-suit because "[th]e invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time." *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138 (Fed. Cir. 1985); *see also In re Omeprazole Patent Litig.*, 483 F.3d 1364, 1381 (Fed. Cir. 2007) ("[h]indsight is not an available analytical mechanism to show obviousness") (citation omitted). Therefore, "[i]t is critical that the question of obviousness not be viewed in the light of the accomplished result." *BOC Health Care, Inc. v. Nellcor Inc.*, 892 F. Supp. 598, 603 (D. Del. 1995) (internal quotation marks and citation omitted).

44. The use of hindsight is prohibited in the obviousness analysis. *KSR*, 550 U.S. at 421 ("A factfinder should be aware, of course, of the distortion cause by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning"); *accord Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1374 n.3 (Fed. Cir. 2008); *Yamanouchi*, 231 F.3d at 1343. It is always inappropriate to "simply retrace[] the path of the inventor with hindsight, discount[] the number and complexity of the alternatives, and conclude[] that the invention ... was obvious." *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d at 1364. An obviousness analysis cannot discount "inventor's insight[]," "willingness to confront and overcome obstacles," and even "serendipity." *Id*. "Hindsight reconstruction and/or the blueprint drawn by the inventor may not

be used to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *Discovision Associates v. Disc Mfg., Inc.*, 25 F. Supp. 2d 301, 345 (D. Del. 1998) (internal quotation marks and citation omitted). Indeed, evidence of how the inventor makes his invention cannot be used to demonstrate obviousness. 35 U.S.C. § 103(a).

45. "The purpose is to assure an appropriate perspective of the decisionmaker, and to focus on conditions as they existed when the invention was made. Good ideas may well appear 'obvious' after they have been disclosed, despite having been previously unrecognized." *Arkie Lures*, 119 F.3d at 956. "[T]he simplicity of new inventions is oftentimes the very thing that is not obvious before they are made." *In re Wanderham*, 378 F.2d 981, 987 (C.C.P.A. 1967). "The fact that the invention seems simple after it is made is not determinative of the question of obviousness." *Id*.

46. Moreover, "[i]n considering motivation in the obviousness analysis, the problem examined is not the specific problem solved by the invention." *Insite Vision Inc. v. Sandoz, Inc.*, 783 F.3d 853, 859-60 (Fed. Cir. 2015) (finding problem faced by person of skill was broader than whether topical azithromycin could be used to treat conjunctivitis) (internal citations omitted). "[A]n overly narrow statement of the problem [can] represent[ ] a form of prohibited reliance on hindsight, [because] [o]ften the inventive contribution lies in defining the problem in a new revelatory way." *Mintz v. Dietz & Watson, Inc.,* 679 F.3d 1372, 1377 (Fed. Cir. 2012); *see also Monarch Knitting Mach. Corp. v. Sulzer Morat Gmbh*, 139 F.3d 877, 880 (Fed. Cir. 1998) ("[d]efining the problem in terms of its solution reveals improper hindsight in the selection of the prior art relevant to obviousness"); *Purdue Pharma L.P. v. Depomed, Inc.*, --- Fed. Appx. ----, 2016 WL 1161229, at *6 (Fed. Cir. Mar. 24, 2016) *quoting same*.

2. Evidence of Non-Obviousness

47. Before ruling on the question of validity of a patent claim, a court must also consider evidence of nonobviousness. This evidence is sometimes referred to as "secondary considerations." *Ruiz*, 234 F.3d at 667. "[E]vidence relating to secondary considerations constitutes independent evidence of nonobviousness and can be quite instructive in the obviousness inquiry." *Sud-Chemie, Inc. v. Multisorb Techs., Inc.*, 554 F.3d 1001, 1008 (Fed. Cir. 2009) (citation and internal quotation marks omitted). "[T]he public and commercial response to an invention is a factor to be considered in determining obviousness, and is entitled to fair weight. The so-called 'secondary considerations' provide evidence of how the patented device is viewed by the interested public: not the inventor, but persons concerned with the product in the objective arena of the marketplace." *Arkie Lures, Inc.*, 119 F.3d at 957 (citation omitted).

48. "[W]hen differences that may appear technologically minor nonetheless have a practical impact, particularly in a crowded field, the decision-maker must consider the obviousness of the new structure in this light. Such objective indicia as commercial success, or filling an existing need, illuminate the technological and commercial environment of the inventor, and aid in understanding the state of the art at the time the invention was made." *Cont'l Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1273 (Fed. Cir. 1991). "[C]ommercial success, long-felt but unresolved need, failure of others, copying and unexpected results" are examples of secondary considerations that may be evidence of non-obviousness. *Ruiz*, 234 F.3d at 662-63.

a) Unexpected or Surprising Beneficial Results

49. "One way for a patent applicant to rebut a *prima facie* case of obviousness is to make a showing of 'unexpected results,' i.e., to show that the claimed invention exhibits some

superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected. The basic principle behind this rule is straightforward — that which would have been surprising to a person of ordinary skill in a particular art would not have been obvious. The principle applies most often to the less predictable fields, such as chemistry, where minor changes in a product or process may yield substantially different results." *In re Soni*, 54 F.3d at 750; *In re Papesch*, 315 F.2d 381, 386–87 (C.C.P.A. 1963) ("If that which appears, at first blush, to be obvious though new is shown by evidence not to be obvious, then the evidence prevails over surmise or unsupported contention and a rejection based on obviousness must fall."); *see also United States v. Adams*, 383 U.S. 39, 51 (1966) (battery not obvious in view that the successful operating characteristics it achieved were "unexpected"); *Lindemann*, 730 F.2d at 1461 ("Though no requirement for such results is present in the statute, 35 U.S.C.A. § 103, … evidence of unexpected results may be strong support for a conclusion of nonobviousness"); *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 2001 WL 1397304, at *13 (S.D. Ind. Oct. 29, 2001).

50. A patentee can demonstrate unexpected results by showing "that the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected. The basic principle behind this rule is straightforward—that which would have been surprising to a person of ordinary skill in a particular art would not have been obvious." *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995). "Evidence developed after the patent grant is not excluded from consideration, for understanding of the full range of an invention is not always achieved at the time of filing the patent application." *Knoll Pharm. Co., Inc. v. Teva Pharms. USA, Inc.*, 367 F.3d 1381, 1384–85 (Fed. Cir. 2004).

51. A finding of "unexpected results" is "tantamount to a finding of nonobviousness." *See Hoganas AB v. Dresser Indus., Inc.*, 9 F.3d 948, 954 n. 28 (Fed. Cir. 1993); *see also KSR,* 550 U.S. at 417 (combinations of known elements not obvious if they create a "new synergy"); *Kao Corp. v. Unilever U.S., Inc.*, 441 F.3d 963, 970 (Fed. Cir. 2006) (rejecting argument that unexpected results cannot overcome the "overwhelming" evidence based on the combination of prior art references).

52. Because "all evidence of nonobviousness must be considered," evidence of unexpected results must be examined when determining whether a patent is obvious. *In re Soni*, 54 F.3d at 750. Both unexpected differences in properties and differences in degree of activity can establish non-obviousness. *In re Wagner*, 371 F.2d 877, 885 (C.C.P.A. 1967).

53. A direct comparison with the prior art is not necessary. *See In re Merchant*, 575 F.2d 865, 869 n.8 (C.C.P.A. 1978) (citing *In re Blondel*, 499 F.2d 1311, 1317 (C.C.P.A. 1974)); *In re Fouche,* 439 F.2d 1237, 1341 (C.C.P.A. 1971) (comparison with unsaturated compound permissible even though closest prior art was a saturated compound because literature "indicate[s] that the unsaturated derivatives are more active than the saturated ones, and [applicant's] evidence showed that the claimed compound was more active than the best of the unsaturated derivates.").

54. Furthermore, it is not necessary that the unexpected properties be known at the time of the invention or disclosed in the patent:

> Evidence developed after the patent grant is not excluded from consideration, for understanding of the full range of an invention is not always achieved at the time of filing the patent application. It is not improper to obtain additional support consistent with the patented invention, to respond to litigation attacks on validity. There is no requirement that an invention's properties and advantages were fully known before the patent application was filed, or that the patent application contains all of the work done in

> studying the invention, in order for that work to be introduced into evidence in response to litigation attack. Nor is it improper to conduct additional experiments and provide later-obtained data in support of patent validity.

Knoll Pharm. Co., 367 F.3d at 1385; *see also Genetics Inst., LLC v. Novartis Vaccines and Diagnostics, Inc.* 655 F.3d 1291, 1307 (Fed. Cir. 2011); *In re Chu*, 66 F.3d 292, 299 (Fed. Cir. 1995) ("We have found no cases supporting the position that a patent applicant's evidence and/or arguments traversing a § 103 rejection must be contained within the specification"); *Daiichi Sankyo Co., Ltd. v. Mylan Pharms. Inc.*, 670 F. Supp. 2d 359, 381 (D.N.J. 2009) ("Secondary considerations extend beyond what was known at the time of the invention and may include later discovered unexpected properties of the invention"); *Janssen Pharmaceutica N.V. v. Mylan Pharms., Inc.*, 456 F. Supp. 2d 644, 672 (D.N.J. 2006) ("In making this determination [of unexpected results], the Court should look at the evidence from both before and after the patent application was filed."); *Forest Labs., Inc. v. Ivax Pharms., Inc.*, 2006 WL 6293849, at *6 (D. Del. Feb. 21, 2006) (applying *Knoll* to deny a motion to exclude later evidence of unexpected results so long as the unexpected results were "consistent with the patented invention"); *In re Cyclobenzaprine Hydrochloride Extended-Release*, 2010 WL 3766530 (D. Del. Sept. 21, 2010) ("If others continue to fail despite having the patent as prior art, such failures may illustrate just how radically different the patent was from past discoveries."); *In re Merchant*, 575 F.2d 865, 869 (C.C.P.A. 1978) ("We are aware of no law requiring that unexpected results relied upon for patentability be recited in the claims."); *Preemption Devices, Inc. v. Minnesota Mining & Mfg. Co.*, 732 F.2d 903, 907 (Fed.Cir. 1984) (permitting reliance on "sales pitch features" not recited in claims for unexpected results, stating that ""[S]ales pitch features" … do not properly belong in claims, the sole function of which is to point out distinctly … [the] composition of matter which is patented, not its advantages.") ; *In re Stemniski*, 444 F.2d 581, 587 (C.C.P.A.

1971) (reversing Board's obviousness rejection to chemical composition, which was structurally similar to prior art compositions, where applicant showed an unexpected use for its claimed compound from the known uses of the structurally similar compounds).

55. Finally, an invention need have only one unexpected superior property when compared to the prior art to overcome a *prima facie* obviousness case, and may be the same or even inferior in other properties. *See, e.g.*, *In re Chupp*, 816 F.2d 643, 646 (Fed. Cir. 1987).

b) Long-Felt Need

56. One of the "factual underpinnings" of an obviousness consideration is whether there was a long-felt but unmet need for the invention; such evidence may be used to rebut an obviousness rejection. *Tec Air, Inc. v. Denso Mfg. Michigan Inc.*, 192 F.3d 1353, 1361 (Fed. Cir. 1999). "[L]ong-felt need is analyzed as of the date of an articulated identified problem and evidence of efforts to solve that problem." *Tex. Instruments Inc. v. U.S. Int'l Trade Comm'n*, 988 F.2d 1165, 1178 (Fed. Cir. 1993); *Perfect Web Technologies, Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1332 (Fed. Cir. 2009) (citing *id.*).

c) Copying

57. Copying is a relevant secondary consideration, even in ANDA cases. *See Ortho-McNeil Pharm., Inc. v. Mylan Labs, Inc.*, 348 F. Supp. 2d 713, 759 (N.D. W. Va. 2004) (explaining that "Mylan's decision to copy LEVAQUIN instead of FLOXIN is significant evidence of non-obviousness," and rejecting Mylan's argument that it "would produce a generic drug without heavily weighing its respective properties"); *Sanofi-Aventis Deutschland Gmbh v. Glenmark Pharmaceuticals Inc.*, USA, 2011 WL 383861 (D.N.J. Feb. 3, 2011) ("Copying, as secondary considerations evincing non-obviousness, is important part of demonstrating non-obviousness even in a pharmaceutical patent case against an ANDA filer because an ANDA filer

is not *required* to copy") (declined to follow on other grounds, *Virnetx, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308 (Fed. Cir. 2014); *Forest Labs., Inc. v. Ivax Pharms., Inc.*, 438 F. Supp. 2d 479, 496 (D. Del. 2006), *aff'd* 501 F.3d 1263 (Fed. Cir. 2007) ("copying of others is particularly telling" because prior art compound "is currently available as a generic drug"; "[t]he success of Lexapro and its benefits compared with other SSRIs is also supported by the efforts of generic drug manufacturers, including Defendants, to copy the claimed invention.").

d) Accolades

58. Acclaim in the industry is another secondary consideration that is relevant to obviousness. *See Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d at 1380; *Rolls-Royce, PLC v. United Technologies Corp.*, 603 F.3d 1325, 1339 (Fed. Cir. 2010); *Institut Pasteur & Universite Pierre Et Marie Curie v. Focarino*, 738 F.3d 1337, 1347 (Fed. Cir. 2013) ("industry praise… provides probative and cogent evidence that one of ordinary skill in the art would not have reasonably expected that a GIIE endonuclease could successfully modify chromosomal DNA in eukaryotic cells.").

e) Failure of Others

59. Failed attempts by others can "be determinative on the issue of obviousness." *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1285 (Fed. Cir. 2000). Indeed, "there can be little better evidence negating an expectation of success than actual reports of failure." *Boehringer Ingelheim Yetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1354 (Fed. Cir. 2003). "If people are clamoring for a solution, and the best minds do not find it for years, that is practical evidence — the kind that can't be bought from a hired expert, the kind that does not depend on fallible memories or doubtful inferences — of the state of knowledge .... If [the patented] device were obvious, other persons skilled in the art would have made it." *In re*

Mahurkar Double Lumen Hemodialysis Catheter Patent Litig., 831 F. Supp. 1354, 1378 (N.D. Ill. 1993), *aff'd* 71 F.3d 1573 (Fed. Cir. 1995).

60. The patent holder does not have to demonstrate why other drug companies failed, only that they did fail. *See Shackelton v. J. Kaufman Iron Works, Inc.*, 689 F.2d 334, 341 (2d Cir. 1982) (reversing obviousness determination based in part on evidence of long felt need and failed efforts by Kaufman to develop its own acceptable product).

f) Skepticism

61. Expressions of skepticism by those in the art are "relevant and persuasive" evidence of nonobviousness. *See Monarch Knitting*, 139 F.3d at 885; *see also Metabolite Labs, Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1368 (Fed. Cir. 2004) ("the record contains evidence of objective indicia that support the jury's nonobviousness verdict. The record, for example, shows that skilled artisans were initially skeptical about the invention."); *Envtl. Designs, Ltd. v. Union Oil Co. of Cal.*, 713 F.2d 693, 697 (Fed. Cir. 1983).

g) Teaching Away

62. "[W]hen the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious." *KSR*, 550 U.S. at 416; *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1305 (Fed. Cir. 2015) ("The district court did not clearly err in finding that the prior art taught away from using 200 ppm BAK in a bimatoprost formulation. As the district court found, the prior art taught that BAK should be minimized in ophthalmic formulations to avoid safety problems"); *U.S. v. Adams*, 383 U.S. 39, 51–52 (1966); *C.W. Zumbiel Co., Inc. v. Kappos*, 702 F.3d 1371, 1383-85 (Fed. Cir. 2012).

h) Commercial Success

63. The commercial success of a product which has a nexus to the invention itself provides evidence that the invention is not obvious. *Al-Site Corp. v. VSI Intern., Inc.*, 174 F.3d 1308, 1325–26 (Fed. Cir. 1999); *see also Goodyear Tire & Rubber Co. v. Ray-O-Vac Co.*, 321 U.S. 275, 279 (1944). Such evidence of commercial success may be demonstrated even if the product being examined infringes under the doctrine of equivalents. *Dome Patent, L.P. v. Rea*, --- F. Supp.2d ----, 2014 WL 2948927, *26 (D.D.C. 2014), *aff'd*, 799 F. 3d 1372, 1383, 115 U.S.P.Q.2d (Fed. Cir. 2015) ("the Court is persuaded that the commercial success of a product that infringes a patent claim under the doctrine of equivalents can inform whether the patent claim is obvious.").

64. The federal circuit has found that "[a] prima facie case of nexus is made when the patentee shows both that there is commercial success, and that the product that is commercially successful is the invention disclosed and claimed in the patent." *Crocs, Inc. v. International Trade Com'n*, 598 F.3d 1294, 1310–11 (Fed. Cir. 2010) While a nexus between the commercial success and the invention itself must be shown, "[i]t is not necessary…that the patented invention be solely responsible for the commercial success, in order for this factor to be given weight appropriate to the evidence, along with other pertinent factors." *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1273 (Fed. Cir. 1991); *see also Pro-Mold and Tool Co., Inc. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1574 (Fed. Cir. 1996) (patent holder's lack of previous experience in the market coupled with its high sales of patented product provided an inference of a nexus between its commercial success and the patented invention).

65. "[A] patentee "need not show that all possible embodiments with the claims were successfully commercialized in order to rely on the success in the marketplace of the

embodiment that was commercialized." *Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc.*, 98 F.3d 1563, 1570 (Fed. Cir. 1996) (affirming judgment patent claims not obvious where challenger asserted that claims were broader than the commercial embodiment).

III. EXCEPTIONAL CASE / ATTORNEY FEES

66. The Patent Act contemplates an award of attorney fees for infringement by an ANDA filing. 35 U.S.C. § 271(e)(4) ("For an act of infringement described in paragraph (2) ... a court may award attorney fees under section 285."). Section 285, in turn, recites that "[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party." 36 U.S.C. § 285. The Supreme Court has held "that an 'exceptional' case is simply one that stands out from others with respect to the substantive strength of a party's litigating position (considering both the governing law and the facts of the case) or the unreasonable manner in which the case was litigated." *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 134 S. Ct. 1749, 1755-57 (2014) (citations omitted—reversing denial of attorney's fees and remanding).

67. The conduct of the party against whom the fees are being asserted should be "viewed together," taken as a whole. *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547 (Fed. Cir. 1989). It makes no difference if there are not actual damages in a case — "[t]hat there were not actual damages does not render the award of attorney fees punitive. Attorney fees are compensatory, and may provide a fair remedy in appropriate cases." *Knorr-Bresme Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337, 1347 (Fed. Cir. 2004).

68. Attorney fees under section 285 may be awarded for time incurred in the litigation of legitimate patent claims. *Interspiro USA, Inc. v. Figgie Int'l Inc.*, 18 F.3d 927 (Fed. Cir. 1994). The federal circuit "has recognized many varieties of misconduct that make a case exceptional for a fee award. These forms of misconduct include willful infringement, inequitable conduct

before the PTO, offensive litigation tactics, vexatious or unjustified litigation, or frivolous filings." *Yamanouchi*, 231 F.3d at 1346-47 (citations omitted)(finding attorney fees justified where infringer filed a "wholly unjustified ANDA certification" and engaged in "misconduct during the litigation that followed"). This also includes the filing of a "baseless" Paragraph IV certification letter. *Takeda Chem. Indus., Ltd. v. Mylan Labs., Inc.*, 549 F.3d 1381, 1388 (Fed. Cir. 2008) (affirming award of more than $ 16 million in attorney fees to patentee based on generic manufacturers filing of a "baseless" Paragraph IV certification letter, which failed to prove *prima facie* case of obviousness).

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IMPAX LABORATORIES, INC., ASTRAZENECA AB, and ASTRAZENECA UK LIMITED, Plaintiffs, v. LANNETT HOLDINGS, INC., and LANNETT COMPANY, INC., Defendants.	)	C.A. No. 14-984-RGA (Consolidated)

EXHIBIT 5

LANNETT'S STATEMENT OF ISSUES OF LAW TO BE LITIGATED AT TRIAL

Pursuant to Local Rule 16.3(c)(5), Lannett submits this statement of issues of law that remain to be litigated. The identification of these issues is based in part on Lannett's current understanding of Plaintiffs' claims. Lannett reserves the right to supplement, amend, or modify this list, for example, to respond to any new issues, arguments, or evidence from Plaintiffs, or in the event of any Court ruling that might raise new issues.

To the extent that Lannett's statement of the issues of fact that remain to be litigated set forth in Exhibit 3 contains issues of law, those issues are incorporated herein by reference. Should the Court determine that any issue identified in this statement as a legal issue is more appropriately considered a factual issue, Lannett incorporates such issues by reference into Exhibit 3.

I. THE ASSERTED CLAIMS OF U.S. PATENT NOS. 6,750,237 AND 7,220,767 ARE NOT INFRINGED

Lannett does not infringe any asserted claim of the '237 Patent or the '767 Patent.

Authorities:

A patent infringement analysis consists of two steps: (1) determining the scope of the claims, a legal issue for the Court (a step that the Court performed in December 2015 when it issued its Memorandum Opinion on claim construction (D.I. 60) and Claim Construction Order (D.I. 64)); and (2) comparing the claims, properly construed, to the accused products, a factual question. *Carroll Touch, Inc. v. Electro Mech. Sys., Inc.*, 15 F.3d 1573, 1576 (Fed. Cir. 1993).

Literal infringement requires a Plaintiff to prove by a preponderance of the evidence that each and every limitation of the asserted claims is literally met by the allegedly infringing products. *Enercon GmbH v. Int'l Trade Comm'n*, 151 F.3d 1376, 1384 (Fed. Cir. 1998); *see also Amhil Enters. Ltd. v. Wawa, Inc.*, 81 F.3d 1554, 1562 (Fed. Cir. 1996) (literal infringement occurs when "the properly construed claim reads on the accused device exactly"); *Laitram Corp. v. Rexnord, Inc.*, 939 F.2d 1533, 1535 (Fed. Cir. 1991) ("The patentee bears the burden of proving infringement by a preponderance of the evidence."); *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1248 (Fed. Cir. 2000) (affirming district court's grant of summary judgment of non-infringement for failure to establish every claim limitation in the accused product). It is improper to compare the accused product with a preferred embodiment in the patent's examples, instead of with the patent's claims. *SRI Int'l. v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1121 (Fed. Cir. 1985); *Martin v. Barber*, 755 F.2d 1564, 1567 (Fed. Cir. 1985). Further, it is the claims of the patent, and not the characteristics of the patentee's product, that control the infringement inquiry. *See, e.g., Martin v. Barber*, 755 F.2d 1564, 1567 (Fed. Cir. 1985) ("Infringement, either

literal or by equivalence, is determined by comparing the accused device with the claims in suit, not with a preferred or commercial embodiment of the patentee's claimed invention.").

Because a dependent claim incorporates all the limitations of the independent claim from which it depends, no asserted dependent claim can be infringed as a matter of law unless each and every element of the underlying independent claim is also infringed. *See Monsanto Co. v. Syngenta Seeds, Inc.*, 503 F.3d 1352, 1359 (Fed. Cir. 2007) ("One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim.").

The reverse doctrine of equivalents is an equitable doctrine designed to prevent unwarranted extension of the claims beyond a fair scope of the patentee's invention. *Roche Palo Alto LLC v. Apotex, Inc.*, 531 F.3d 1372 (Fed. Cir. 2009). Where a device is so far changed in principle from a patented article that it performs the same or similar function in a substantially different way, but nevertheless falls within the literal words of the claim, the reverse doctrine of equivalents may be used to restrict the claim and defeat the patentee's action for infringement. *Id*.

Infringement allegations under 35 U.S.C. § 271(e)(2) are premised upon an artificial act of infringement (*i.e.*, the filing of an ANDA) and the infringement inquiry is hypothetical, requiring the court to compare the claims with the product described in the ANDA. *Bayer AG*, 212 F.3d at 1248. The proper focus for determining infringement under § 271(e)(2)(A) is on "what the ANDA applicant will likely market if its application is approved, an act that has not yet occurred." *Glaxo Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1567 (Fed. Cir. 1997). The "hypothetical inquiry is properly grounded in the ANDA application and the extensive materials typically submitted in its support." *Id.* at 1569. "The relevant inquiry is whether the patentee

has proven by a preponderance of the evidence that the alleged infringer will likely market an infringing product. What is likely to be sold, or preferably, what will be sold, will ultimately determine whether infringement exists." *Id.* at 1570.

Where there is no literal infringement, the Court must conduct an analysis under the doctrine of equivalents. *Hilton Davis Chem. Co. v. Warner-Jenkinson Co.*, 62 F.3d 1512, 1522 (Fed. Cir. 1995) ("The trial judge does not have discretion to choose whether to apply the doctrine of equivalents when the record shows no literal infringement."), *rev'd on other grounds*, 520 U.S. 17 (1997). "The doctrine of equivalents allows the patentee to claim those insubstantial alterations that were not captured in drafting the original patent claim but which could be created through trivial changes." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co*., 535 U.S. 722, 733 (2002).

Under the doctrine of equivalents, "[a]n element in the accused product is equivalent to a claim limitation if the differences between the two are 'insubstantial' to one of ordinary skill in the art." *Wavetronix v. EIS Elec. Integrated Sys.*, 573 F.3d 1343, 1360 (Fed. Cir. 2009). A patentee may prove infringement under the doctrine of equivalents "by showing on a limitation by limitation basis that the accused product performs substantially the same function in substantially the same way with substantially the same result as each claim limitation of the patented product." *Crown Packaging Tech., Inc. v. Rexam Beverage Can Co*., 559 F.3d 1308, 1312 (Fed. Cir. 2009). However, "equivalency [would have to] be proven with 'particularized testimony and linking arguments.'" *Texas Instruments Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1566 (Fed. Cir. 1996). In addition, under the "all elements rule," the doctrine of equivalents may not be applied in such a way that vitiates, or nullifies, claim limitations. *See Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17 (1997).

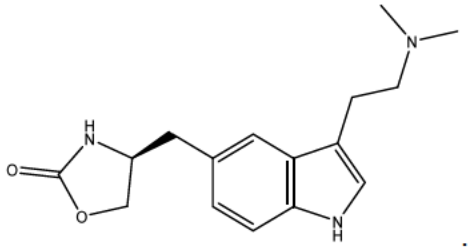
The doctrine of equivalents can also not be applied in cases where a patent drafter discloses but declines to claim subject matter because such action dedicates that unclaimed subject matter to the public. *Johnson & Johnston Associates Inc. v. R.E. Service Co., Inc.*, 285 F.3d 1046 (Fed.Cir. 2002). Application of the doctrine of equivalents to recapture subject matter deliberately left unclaimed would conflict with the primacy of the claims in defining the scope of the patentee's exclusive right. *Id*.

Ensnarement bars a patentee from asserting a scope of equivalency that would encompass, or "ensnare," the prior art. *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc*. 567 F.3d 1314 (Fed.Cir. 2009).

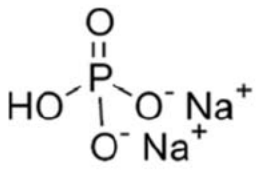
II. CLAIM CONSTRUCTION

When interpreting claims, "courts do not rewrite claims; instead [they] give effect to the terms chosen by the patentee." *K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1364 (Fed. Cir. 1999). It is "one of the cardinal sins of patent law [to] rea[d] a limitation from the written description into the claims." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1320 (Fed. Cir. 2005) (en banc). "[W]e know of no principle which would authorize us to read into a claim an element which is not present. . . . [I]f we once begin to include elements not mentioned in the claim, in order to limit such claim . . . we should never know where to stop." *McCarty v. Lehigh Valley Rail Co.*, 160 U.S. 110, 116 (1895).

The Court construed the following disputed claim terms as follows. *See* Claim Construction Order (D.I. 64):

Claim Term	Court's Construction
preambles	Limiting.
"zolmitriptan"	Compound having the chemical name (S)-4-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-2-oxazolidinone and chemical structure: 
"buffer," "buffered," and "in a buffer"	Formulations or material(s) therein that resist change in pH on adding acid or alkali or on dilution with solvent.

In addition, the Court adopted the following agreed-upon constructions. *See id.*

Claim Term	Agreed Construction
"disodium phosphate"	Compounds containing the basic structure as depicted in Figure 2 below, including all forms thereof, including sodium hydrogen phosphate; disodium hydrogen orthophosphate; sodium phosphate dibasic; dibasic sodium phosphate; disodium phosphate dodecahydrate; disodium phosphate heptahydrate; disodium phosphate dihydrate; and anhydrous disodium phosphate.  **Figure 2**

{01140355;v1 }

Claim Term	Agreed Construction
"pH of the formulation is 5"	The pH is 5 +/- 0.04.

III. THE ASSERTED CLAIMS OF U.S. PATENT NOS. 6,750,237 AND 7,220,767 ARE INVALID

The asserted claims of the '237 and '767 Patents are invalid.

Authorities:

Under 35 U.S.C. § 282, a patent issued by the United States Patent and Trademark Office ("PTO") is presumed to be valid. Because of this presumption, a party seeking to invalidate a patent bears the burden of proving invalidity by facts supported by clear and convincing evidence. *Beckson Marine, Inc. v. NFM, Inc.*, 292 F.3d 718, 725 (Fed. Cir. 2002). "[T]here is no heightened burden of proof when a reference was previously considered by the PTO, and no lowered burden of proof if a defendant raises a new reference or argument during litigation." *Sciele Pharma v. Lupin Ltd.*, 684 F.3d 1253, 1260 (Fed. Cir. 2012) (holding prior art that was considered by the PTO nonetheless raised a substantial question of invalidity).

However, "new evidence supporting an invalidity defense may 'carry more weight' in an infringement action than evidence previously considered by the PTO." *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2251 (2011). "Simply put, if the PTO did not have all material facts before it, its considered judgment may lose significant force." *Id.*

The presumption of validity is "far from determinative," and a trial court is free to consider the evidence and decide the issue differently from the PTO. *See AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1245 (Fed. Cir. 2003).

A claim must be interpreted the same way in determining infringement and invalidity. *Amazon.com, Inc. v. Barnesandnobel.com, Inc.*, 239 F.3d 1343, 1351 (Fed. Cir. 2001).

A. The Asserted Claims are Invalid for Anticipation

The asserted claims of the '237 and '767 Patents are invalid as anticipated.

Authorities:

Under 35 U.S.C. § 102, an invention is anticipated where:

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, or
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for a patent in the United States, or
>
> * * * * *
>
> (e) The invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language

35 U.S.C. § 102(a), (b), (e) (pre-AIA).

Claimed subject matter is "anticipated" when it is not new; that is, when it was previously known. *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075 (Fed.Cir. 2008). Invalidation on this ground requires that every element and limitation of the claim was previously described in a single prior art reference, either expressly or inherently, so as to place a person of ordinary skill in possession of the invention. *Id.* Anticipation, a question of fact. *See Orion IP, LLC v. Hyundai Motor Am.*, 605 F.3d 967, 974-75 (Fed. Cir. 2010); *King Pharm., Inc. v. Eon Labs, Inc.*,

616 F.3d 1267, 1274 (Fed. Cir. 2010). An anticipatory reference must be enabling. *Akzo N.V. v. U.S. Int'l Trade Comm'n*, 808 F.2d 1471, 1479 (Fed. Cir. 1986). The patentee, however, bears the burden of overcoming the presumption of prior art enablement by a preponderance of the evidence. *See Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1355–56 (Fed. Cir. 2003).

A prior art reference can anticipate when the claim limitations not expressly found in that reference are nonetheless inherent in it. *Atlas Powder Co. v. IRECO, Inc.*, 190 F.3d 1342, 1346 (Fed. Cir. 1999). A prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference. *Verizon Services Corp. v. Cox Fibernet Virginia, Inc.*, 602 F.3d 1325 (Fed. Cir. 2010). Questions concerning the motivations of one skilled in the art, or whether the prior art teaches away from claimed subject matter, are not relevant to anticipation. *Bristol–Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1378 (Fed. Cir. 2001). Moreover, the disclosure of multiple examples in a single item of prior art does not render one example less anticipatory. *Leggett & Platt, Inc. v. VUTEk, Inc.*, 537 F.3d 1349, 1356 (Fed. Cir. 2008). Inherency arises when a limitation not expressly found in a prior art reference is necessarily present based on what that prior art reference conveys to those of ordinary skill in the art. *See Abbott Labs. v. Baxter Pharm. Prods., Inc.*, 471 F.3d 1363, 1368 (Fed. Cir. 2006); *Smithkline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1343 (Fed. Cir. 2005); *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1047 (Fed. Cir. 1993). It is not necessary that the prior art actually recognize or achieve the results of the claimed invention. *See Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1376 (Fed. Cir. 2001) ("Newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent.").

If an item of prior art does not expressly disclose a claim limitation that is a member of a group but discloses the group, this item of prior art can nevertheless anticipate the claim if the claimed member of the group would at once be envisaged by a person skilled in the art reading the disclosure of the group. *Abbvie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Trust*, 764 F.3d 1366, 1379 (Fed. Cir. 2014).

Material not explicitly contained in a single, prior art document may still be considered for purposes of anticipation if that material is incorporated by reference into the document. *Advanced Display Systems, Inc. v. Kent State University*, 212 F.3d 1272 (Fed. Cir. 2000).

B. The Asserted Claims are Invalid for Obviousness

The asserted claims of the '237 and '767 Patents are invalid for obviousness.

Authorities:

Section 103(a) of the Patent Statute, 35 U.S.C., provides:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title [35 U.S.C. § 102], if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

35 U.S.C. § 103(a) (2006).

Obviousness is a question of law based on factual determinations that include: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the prior art and the claims at issue; and (4) certain secondary considerations that may be relevant as indicia of obviousness or non-obviousness. *KSR Int'l Co. v Teleflex Inc.*, 550 U.S. 398, 406 (2007) (*citing Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966)). To establish that

a claimed invention was obvious, one must show, by clear and convincing evidence, that "the invention described in the patent would have been obvious to a person of ordinary skill in the art at the time the invention was made." *Aventis Pharma S.A. v. Hospira, Inc.*, 743 F. Supp. 2d 305, 336 (D. Del. 2010) (citing *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1359-60 (Fed. Cir. 2007)).

"Prior art" in the obviousness context includes the art identified in § 102. *OddzOn Prods., Inc. v. Just Toys, Inc.*, 122 F.3d 1396,1401 (Fed. Cir. 1997). Printed publications and patents constitute prior art if they were published (1) before the inventor named on the patent invented the claimed subject matter or (2) more than one year before the date that the application leading to the patent at issue was filed. 35 U.S.C. § 102(a)-(b). U.S. patent applications filed before the date the inventor named on the patent-in-suit invented the claimed subject matter are also prior art. 35 U.S.C. § 102(e).

For purposes of obviousness, the scope and content of the prior art includes all "analogous" prior art. *Comaper Corp. v. Antect, Inc.*, 596 F.3d 1343, 1351 (Fed. Cir. 2010) ("Analogous art is that which is relevant to a consideration of obviousness under 35 U.S.C. § 103."). Prior art is analogous if "the art is from the same field of endeavor, regardless of the problem addressed" by the reference. *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1237 (Fed. Cir. 2010). Prior art is also analogous if "the reference . . . is reasonably pertinent to the particular problem with which the inventor is involved," even if it is not in the patentee's field of endeavor. *Id.*

The person of ordinary skill in the art ("POSA") is a legal construct—a hypothetical person who is placed in the position of being aware of all of the relevant prior art. *In re GPAC, Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). "A person of ordinary skill is also a person of ordinary creativity, not an automaton." *KSR*, 550 U.S. at 421.

"Factors for determining the level of ordinary skill in the art may include: (1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field." *Daiichi Sankyo Co. v Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007). In determining the level of ordinary skill in the art, the relevant art "is defined by the nature of the problem confronting the would-be inventor." *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 716 (Fed. Cir. 1991).

For an obviousness analysis, it will often be necessary to look to: (1) "interrelated teachings of multiple patents"; (2) "the effects of demands known to the design community or present in the marketplace"; and (3) "the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR Int 'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 418 (2007).

"The question is not whether there would be some motivation to try, or even substantial motivation to try, but rather whether it would have been *obvious* to a POSITA to try, as judged on a clear and convincing evidence standard." *Pfizer Inc. v. Teva Pharm. USA, Inc.*, 803 F. Supp. 2d 409, 444 (E.D. Va. 2011) (emphasis in original). And a motivation to combine teaching from prior art to achieve a claimed invention "may be found in any number of sources, including common knowledge, the prior art as a whole, or the nature of the problem itself." *Pfizer*, 480 F.3d at 1362 (quoting *Dystar Textilfarben GmbH v. C.H. Patrick Co.*, 464 F.3d 1356, 1361 (Fed. Cir. 2006)). "[S]tructural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions, creates a prima facie case of obviousness." *In re Dillon*, 919

F.2d 688, 692 (Fed. Cir. 1990) (en banc). But, under *KSR*, the reason or motivation "may come from any number of sources and need not necessarily be explicit in the prior art." *Otsuka*, 678 F.3d at 1292. Moreover, there is no requirement that "the motivation be the *best* option, only that it be a *suitable* option from which the prior art did not teach away." *PAR Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1197-98 (Fed. Cir. 2014).

"One of the ways in which a patent's subject matter can be proved obvious is by noting that there existed at the time of invention a known problem for which there was an obvious solution encompassed by the patent's claims." *KSR*, 550 U.S. at 419-20; *see also Dippin' Dots*, 476 F.3d at 1345 ("The motivation for DDI to make these trivial modifications [to the process used to make the commercial product] is readily apparent from the problem to be solved. Someone of ordinary skill in the art of ice cream retailing seeking to commercially develop the inventive kernel found at Festival Market, would immediately seek the appropriate temperature ranges within which to store and serve the product.").

"When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp." *KSR*, 550 U.S. at 402. In such a case, "it is likely the product not of innovation but of ordinary skill and common sense." *Id.* at 421. The fact that a combination or improvement was obvious to try might in some circumstances show the patent was obvious under § 103. *See, e.g., id.* Further, "[w]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Applied Materials, Inc.*, 692 F.3d 1289, 1295 (Fed. Cir. 2012) (citation omitted).

"Obviousness does not require absolute predictability of success ... [A]ll that is required is a reasonable expectation of success." *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed Cir. 2006) (citation omitted); *see also Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 (Fed. Cir. 2007) ("[C]ase law is clear that obviousness cannot be avoided simply by showing some degree of unpredictability in the art so long as there was a reasonable probability of success.").

The determination of what one of ordinary skill understood and would have expected is fixed before the effective filing date of the claimed invention, and any advantages or results that were not ordinarily within the contemplation of the patentee should be discounted. *Bristol-Myers Squibb Co. v. Teva Pharmaceuticals USA, Inc.*, 769 F.3d 1339 (Fed. Cir. 2014).

In the context of obviousness, a reference must be considered for all that is taught – disclosures that teach away from the invention as well as disclosures that point toward and teach the invention. *See In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1998). A reference only teaches away if it would have led a person of ordinary skill in the art in a direction that is different than the direction taken by the inventor. *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 885 (Fed. Cir. 1998). "The degree of teaching away will of course depend on the particular facts; in general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by [the inventor]." *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994).

1. Prima Facie Obviousness

If evidence is presented establishing a prima facie case of invalidity, the opponent of invalidity must come forward with evidence to counter the prima facie challenge. *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348 (Fed. Cir. 2007). For example, optimization of a range or other variable within the claims flows from the normal desire of scientists or artisans to improve upon

what is already generally known, and accordingly the discovery of an optimum value of a result effective variable is ordinarily within the skill of the art. *See id.* Accordingly, it is not inventive to discover the optimum or workable ranges by routine experimentation. *Id.*

Once a prima facie challenge is made, the patentee can attempt to rebut the challenge with a showing of secondary considerations. *Id.* However, evidence with any such showing must be commensurate in scope with the claims, that is, there must be a nexus between the asserted secondary consideration, such as unexpected result, and the claimed invention. *Ortho-McNeil Pharmaceutical, Inc. v. Teva Pharmaceuticals Industries, Ltd.*, 344 Fed. Appx. 595 (Fed. Cir. 2009). Put another way, the evidence of unexpected results, or any alleged secondary consideration, must be shown to be commensurate in scope with, that is, coextensive, with the scope of the claim. *Millennium Pharmaceuticals, Inc. v. Sandoz Inc.*, 2015 WL 4966438, (Fed.Cir. 2015). Accordingly, it is error to base a finding of nonobviousness on secondary considerations, including unexpected results, that are not commensurate with the full scope of the patents claims. *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952 (Fed. Cir. 2014).

2. Secondary Considerations of Obviousness

Simultaneous invention by others supplies an indicia of obviousness. *See, e.g., Geo. M. Martin Co. v. Alliance Machine Systems Int'l LLC*, 618 F.3d 1294, 1304 (Fed. Cir. 2010). Multiple instances of simultaneous invention, may prevent secondary considerations of nonobviousness from creating a reasonable dispute as to obviousness. *Id.*

3. Secondary Considerations of Non-Obviousness

Once a *prima facie* case of obviousness has been established, the burden shifts to the patentee to come forward with evidence of secondary considerations demonstrating non-obviousness. *See, e.g. Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1360 (Fed. Cir. 2007).

However, in order for secondary considerations to be relevant, the patentee bears the burden of demonstrating a nexus between the alleged secondary consideration relied upon and the features of the claimed invention. *See, e.g., Wyers v. Masterlock*, 616 F.3d 1231, 1246 (Fed. Cir. 2010). Evidence of secondary considerations "must be commensurate in scope with the claims which the evidence is offered to support." *MeadWestVaco Corp. v. Rexam Beauty & Closures, Inc.*, 731 F.3d 1258, 1264-65 (Fed. Cir. 2013).

Secondary considerations of nonobviousness do not control the obviousness conclusion when there is a strong showing of obviousness. *See, e.g., Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1372 (Fed. Cir. 2007); *see also Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007) (holding that the objective considerations of non-obviousness presented, including substantial evidence of commercial success, praise, and long-felt need, were inadequate to overcome a strong showing of obviousness). Nonobviousness is assessed by reference to the claimed invention, and not by reference to properties that cannot ultimately be derived from the claims. *TorPharm Inc. v. Ranbaxy Pharms. Inc.*, 336 F.3d 1322, 1331 (Fed. Cir. 2003).

(a) Commercial Success

"The secondary consideration of commercial success exists largely to provide a means for patentees to show in close cases that the subject matter that appears obvious is in law unobvious because a high degree of commercial success permits the inference that others have tried and failed to reach a solution." *Syntex (U.S.A.) LLC v. Apotex, Inc.*, 407 F.3d 1371, 1383 (Fed. Cir. 2007) (citing *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1376-1377 (Fed. Cir. 2005)).

If a patentee claims commercial success, it must show some connection or nexus between the commercial success and the claims of the patent before the commercial success can be

considered probative of whether the patent is nonobvious. *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988). "[I]f the commercial success is due to an unclaimed feature of the [invention], the commercial success is irrelevant." *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1312 (Fed. Cir. 2006). Likewise, "if the feature that creates the commercial success was known in the prior art, the success is not pertinent." *Id.*

Nexus cannot be established by reference to what is allowing the product to reach the shelves; the nexus must be shown by the relationship between the novel features of the patented invention and what is driving the sales of the product. *AstraZeneca LP v. Breath Ltd.*, 2015 WL 777460 (D.N.J. Feb. 13, 2015) (*aff'd AstraZeneca LP v. Breath Ltd*., 603 Fed. Appx. 999 (Fed. Cir. 2015). Accordingly, it is improper to equate regulatory compliance with evidence of nonobviousness. *Id*.

Commercial success is not always indicative of nonobviousness. For example, the commercial success of an invention "might be due not to the invention itself but to skillful marketing of the product embodying the invention." *Ritchie v. Vast Res., Inc.*, 563 F.3d 1334, 1336 (Fed. Cir. 2009). And "[c]ommercial success due only to superior business acumen, or effective advertising, is of no relevance" to a determination of obviousness. *Soldier Removal Co. v. U.S. Int'l Trade Comm'n*, 582 F.2d 628, 637 (C.C.P.A. 1978). Furthermore, commercial success is not significantly probative if others in the field would have been deterred or inhibited from placing the product on the market by other forces, such as rights to exclude others from practicing the invention and/or impediments such as the burdens of regulatory approval (e.g. FDA approval). *Merck & Co., Inc. v. Teva Pharma. USA, Inc*., 395 F.3d 1364, 1377 (Fed. Cir. 2005). If a patentee can establish a nexus between commercial success and the patented invention, the challenger then bears the burden to show that the success was due to advertising or

other extraneous factors. *See, e.g., J.T. Eaton & Co. v. Atlantic Paste & Glue Co.*, 106 F.3d 1563, 1571 (Fed. Cir. 1997).

(b) Copying

Evidence of copying is not persuasive as objective evidence of non-obviousness in the ANDA context. *See Allergan, Inc. et al. v. Watson Labs., Inc.-Florida*, No. 09-cv-511 (GMS), 869 F. Supp. 2d 456, 485 (D. Del. March 31, 2012) ("as several courts have recognized, demonstration that a defendant has copied a patented invention is not compelling evidence of non-obviousness in the Hatch-Waxman context due to the unique nature of the ANDA process."); *Santarus, Inc. v. Par Pharm, Inc.*, 720 F. Supp. 2d 427, 459 (D. Del. 2009) (where evidence of copying was only an accused ANDA generic, the evidence was "not persuasive objective evidence of non-obviousness."); *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 775 F. Supp. 2d 985, 1017 (E.D. Mich. 2011) ("As evidence of commercial success or copying, Novo cites the fact that six major generic drug manufacturers have filed ANDAs for repaglinide. That argument has been rejected by the Federal Circuit."); *Purdue Pharma Prods. L.P. v. Par Pharm., Inc.*, 377 Fed. App'x 978, 983 (Fed. Cir. 2009) ("[W]e do not find compelling Purdue's evidence of copying in the ANDA context where a showing of bioequivalency is required for FDA approval.").

(c) Failure of Others

Failed attempts by others can "be determinative on the issue of obviousness." *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1285 (Fed. Cir. 2000). While failure of others may in some instances support a finding of non-obviousness, failure by others is not significant where there was only a brief time period during which manufacturers sought a solution

to the problem allegedly solved by the claimed subject matter. *See, e.g.*, *B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.*, 72 F.3d 1577, 1583 (Fed. Cir. 1996).

Post-art failures are irrelevant to the obviousness analysis. *AstraZeneca LP v. Breath Ltd.*, No. 08–1512, 2015 WL 777460 (D.N.J. Feb. 13, 2015) (*aff'd AstraZeneca LP v. Breath Ltd*., 603 Fed. Appx. 999 (Fed.Cir. 2015).

(d) Surprising or Unexpected Results

Evidence of unexpected results can be used in an effort to rebut a prima facie case of obviousness, but it does not necessarily do so. *Bristol-Myers Squibb Co. v. Teva Pharmaceuticals USA, Inc*., 752 F.3d 967 (Fed. Cir. 2014). To be particularly probative, evidence of unexpected results must establish that there is a difference between the results obtained and those of the closest prior art, and that the difference would not have been expected by one of ordinary skill in the art at the time of the invention. *Id.* When claimed ranges are involved, the patentee has the burden of establishing that the claimed range produces new and unexpected results over the prior art range. The need to conduct experimentation that involves the routine application of a known problem solving strategy does not rebut obviousness since it is the work of a skilled artisan, not an inventor. *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348 (Fed. Cir. 2007).

In order for alleged unexpected results to be probative of nonobviousness, it must be proved that "there actually is a difference between the results obtained through the claimed invention and those of the prior art," and that "the difference actually obtained would not have been expected by one skilled in the art at the time of invention." *In re Freeman*, 474 F.2d 1318, 1324 (C.C.P.A. 1973) (citations omitted). "[W]hen unexpected results are used as evidence of nonobviousness, the results must be shown to be unexpected compared with the closest prior

art." *In re Baxter Travenol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991), citing *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984).

Further, the Court must consider "what properties were expected." *Pfizer*, 480 F.3d at 1371; *accord In re Mageli*, 470 F.2d 1380, 1384-85 (C.C.P.A 1973) ("Unobviousness, however, cannot be predicated on superiority alone. Obviousness depends on what those skilled in the art would *expect*.") (emphasis in original). Whether a particular property is unexpectedly superior is determined in the context of a person of ordinary skill in the art. *In re Geisler*, 116 F.3d 1465, 1469 (Fed. Cir. 1997).

Moreover, while unexpected superiority, when proved, is a factor to be considered, it is not sufficient to overcome a strong showing of obviousness. *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1372 (Fed. Cir. 2007).

(e) Teaching Away or Skepticism

"[W]hen the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious." *KSR Int'l*, 550 U.S. at 416. A reference may teach away when a POSA reading it "would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). But the disclosure of an alternative does not teach away from other alternatives unless it criticizes, discredits, or otherwise discourages them. *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004). Furthermore, it is not proper to evaluate the obviousness of a claimed composition based on a functional limitation that is not present in the claim, including to consider whether the prior art teaches away from the use of formulation as having a particular functional limitation if that

limitation is not expressly recited in the claims. *Senju Pharmaceutical Co. v. Lupin Ltd.*, 780 F.3d 1337 (Fed. Cir. 2015).

Expressions of skepticism by those in the art are "relevant and persuasive" evidence of nonobviousness. *See Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 885 (Fed. Cir. 1998). The secondary consideration of skepticism by others typically refers to situations where the alleged invention has already been conceived, and others are skeptical about whether it will work. *See Hughes Tool Co. v. Dresser Indus., Inc.*, 816 F.2d 1549, 1556 (Fed. Cir. 1987).

(f) Long-Felt Need

Establishing long-felt need requires objective evidence that a recognized problem existed in the art for a long period of time without solution. *See Iron Grip Barbell Co., Inc. v. York Barbell Co., Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004) ("Absent a showing of long-felt need or the failure of others, the mere passage of time without the claimed invention is not evidence of nonobviousness."). The need must have been a persistent one that was recognized by those of ordinary skill in the art. *Orthopedic Equipment Co., Inc. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 1382 (Fed. Cir. 1983), *abrogated on other grounds by Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F.3d 1276 (Fed. Cir. 2011) ("Although the invention did achieve a result desirable in all businesses which stock goods, there was no evidence that the industry perceived a decrease in inventory as a 'long felt but unsolved need'"). One looks to the filing date of the challenged invention to assess the presence of a long-felt and unmet need. *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877 (Fed. Cir. 1998). The relevant secondary consideration is "long-felt but unsolved need," not long-felt need in isolation; accordingly,

evidence of contemporaneous development negates any suggestion that a need, even if it is shown to exist, was unmet. *Id.*

(g) Licensing

A patentee may establish the secondary consideration of licensing of the patents-in-suit by demonstrating that (i) the license is attributable to a belief in the validity of the patents, and (ii) a nexus between the licenses and the claimed subject matter. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1539 (Fed. Cir. 1983).

IV. RELIEF

A. Plaintiffs Are Not Entitled to an Injunction

Authorities:

Under 35 U.S.C. § 271(e)(4),

> (4) For an act of infringement described in paragraph (2)-
> (A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,
> (B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product,
> (C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product.
> (D) The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in paragraph

> (2), except that a court may award attorney fees under section 285.

35 U.S.C. § 271(e)(4).

"According to well-established principles of equity, a plaintiff seeking a permanent injunction must satisfy a four-factor test before a court may grant such relief. A plaintiff must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction." *eBay v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006). In *Ebay*, the Supreme Court of the United States rejected what it perceived to be the Federal Circuit's general rule that a permanent injunction will issue once infringement and validity have been adjudged, and that only in exceptional circumstances will such relief be denied. *Id*. at 394.

B. Whether This Is an Exceptional Case

Plaintiffs have not established that this is an exceptional case pursuant to 35 U.S.C. § 285. Lannett, on the other hand, has established that this is an exceptional case pursuant to 35 U.S.C. § 285.

Authorities:

Under 35 U.S.C. § 285, "in exceptional cases [the Court] may award reasonable attorney fees to the prevailing party." 35 U.S.C. § 285. Section § 285 provides discretion where it would be grossly unjust that the prevailing party be left to bear the burden of its own counsel fees, which prevailing litigants normally bear. *Badalamenti v. Dunham's Inc.*, 896 F.2d 1359, 1364 (Fed. Cir. 1990). "[A]n 'exceptional' case is simply one that stands out from others with respect to the substantive strength of a party's litigating position (considering both the governing law and the

facts of the case) or the unreasonable manner in which the case was litigated. District courts may determine whether a case is 'exceptional' in the case-by-case exercise of their discretion, considering the totality of the circumstances." *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 134 S. Ct. 1749, 1756 (2014).

A patentee initiating litigation on a patent known to be invalid or not infringed is conduct offensive to public policy, and can provide a basis for granting attorney fees. *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 878 (Fed. Cir. 1985).

EXHIBIT 6 – JOINT EXHIBIT LIST						
JX	**DX**	**PX**	**Date**	**Description**	**Beg Bates No.**	**End Bates No.**
JX-1		1	6/15/2004	Patent: U.S. Patent No. 6,750,237 B1, Issued to Dearn, et al.	ZOMIG00115627	ZOMIG00115630
JX-2		2	5/22/2007	Patent: U.S. Patent No. 7,220,767 B2, Issued to Dearn, et al.	ZOMIG00115623	ZOMIG00115626
JX-3	5	9	12/16/1999	Patent: International Patent Application No. WO 99/064044, Issued to Marquess, et al.	ZOMIG00117592	ZOMIG00117781
JX-4	1, 4	10	12/4/2001	Patent: U.S. Patent No. 6,326,401 B1, Issued to Chauveau, et al.	ZOMIG00116736	ZOMIG00116742
JX-5	8	11	2/5/2002	Patent: U.S. Patent No. 6,344,449 B1, Issued to Rudolf, et al.	ZOMIG00116743	ZOMIG00116872
JX-6	13	12	3/12/1985	Patent: U.S. Patent No. 4,504,470, Issued to Uda, et al.	ZOMIG00116611	ZOMIG00116619
JX-7	9	13	1/9/1996	Patent: U.S. Patent No. 5,482,931, Issued to Harris, et al.	ZOMIG00116687	ZOMIG00116693
JX-8	16	15	1/22/1998	Patent: International Patent Application No. WO 98/02187, Issued to Penkler, et al.	ZOMIG00116326	ZOMIG00116376
JX-9	77	16	8/22/1996	Article: Barrow, A., et al., The Absorption, Pharmacodynamics, Metabolism and Excretion of C-Sumatriptan Following Intransaal Administration to the Beagle Dog, Biopharmaceutics & Drug Disposition, Vol. 18:443-458 (1997)	ZOMIG00116441	ZOMIG00116456
JX-10	14	18	9/23/1921	Article: McIlvaine, T.C., A Buffer Solution for Colorimetric Comparison, The Journal of Biological Chemistry, Vol. 49:183-186 (1921)	ZOMIG00116573	ZOMIG00116576

JX	DX	PX	Date	Description	Beg Bates No.	End Bates No.
JX-11	106	53	3/30/1995	Article: Glen, R., et al., Computer-Aided Design and Synthesis of 5-Substituted Tryptamines and Their Pharmacology at the 5-HT1D Receptor: Discovery of Compounds with Potential Anti-Migraine Properties, Journal of Medical Chemistry, Vol. 38:3566-3580 (1995)	ZOMIG00115829	ZOMIG00115843
JX-12	21	88	9/26/1996	Patent: International Patent Application No. WO 96/29074, Issued to Johnson, et al.	ZOMIG00123517	ZOMIG00123575
JX-13	68	134	1994	Article: Boulton, D., et al., The Stability of an Enalapril Maleate Oral Solution Prepared from Tablets, Australian Journal of Hospiral Pharmacy, Vol. 24, Issue 2:151-156 (1994)		
JX-14	65	138	1986	Book: Connors, K., et al., Chemical Stability of Pharmaceuticals: A Handbook for Pharmacists, 2nd Ed., John Wiley & Sons, Inc.: New York (1986)		
JX-15	75	139	Mar-64	Article: Fabricant, N., The pH of the Throat, Nose, and Ear, The Eye, Ear, Nose and Throat Monthly, Vol. 43, Issue 3:60, 76 (1964)		
JX-16	71	142	1986	Article: Gupta, V., et al., Stability of Hydralazine Hydrochloride in Aqueous Vehicles, Journal of Clinical and Hospital Pharmacy, Vol. 11:215-223 (1986)		
JX-17	67	148	February 1995	Article: Nahata, M., et al., Stability of Cisapride in a Liquid Dosage Form at Two Temperatures, The Annals of Pharmacotherapy, Vol. 29:125-126 (1995)		

JX	DX	PX	Date	Description	Beg Bates No.	End Bates No.
JX-18	78	214	1998	Article: Behl, C.R., et al., Effects of Physicochemical Properties and Other Factors on Systemic Nasal Drug Delivery (1998)		
JX-19	10			WO 97/25988 (Iyengar)	ZOMIG00123101	ZOMIG00123163
JX-20	11			WO 98/47535 (Watts)	ZOMIG00123271	ZOMIG00123314
JX-21	12			US Patent 5,4443,833 (Clark)	ZOMIG00116680	ZOMIG00116686
JX-22	15			WO1998/002186 (Penkler I)	ZOMIG00123357	ZOMIG00123385
JX-23	22			US 5,705,520 (Craig)	ZOMIG00129049	ZOMIG00129054
JX-24	23			US 4,502,616 (Meierhoefer)	ZOMIG00116604	ZOMIG00116610
JX-25	28			US 4,782,047 (Benjamin)	ZOMIG00116620	ZOMIG00116625
JX-26	29			US 5,397,771 (Bechgaard et al.)	ZOMIG00116644	ZOMIG00116679
JX-27	30			EP 0417930 (Fujioka)	ZOMIG00116421	ZOMIG00116679
JX-28	31			EP 0486854 (Bolasco)	ZOMIG00116465	ZOMIG00116468
JX-29	32			EP 0489217 (Tosi)	ZOMIG00116469	ZOMIG00116475
JX-30	33			WO 99/40900 (Alam).	ZOMIG00117559	ZOMIG00117591
JX-31	34			US 5,037,845 – Oxford	ZOMIG00123925	ZOMIG00123939
JX-32	36			US 5,484,776 (Racz)	ZOMIG00129002	ZOMIG00129009
JX-33	37			US 5,374,659 (Gowan)		
JX-34	39			US 5,215,755 (Roche)		
JX-35	40			US 7,727,552 (Ukai)		
JX-36	41			US 6,045,778 (Jager)		
JX-37	42			US 4,226,848 (Nagai)		

JX	DX	PX	Date	Description	Beg Bates No.	End Bates No.
JX-38	73			Dimerization of sumatriptan as an efficient way to design a potent, centrally and orally active 5-HT1b agonist, Perez et al., Bioorganic & Medicinal Chemistry Letters 8 (1998) 675-680 (Perez)		
JX-39	74			Multiple-Attack Efficacy and Tolerability of Sumatriptan Nasal Spray in the Treatment of Migraine, Diamond et. al., Arch Fam Med. 1998; 7:234-240 (Diamond)		
JX-40	76			Po and Senozan, The Henderson-Hasselbach Equation: Its History and Limitations, Journal of Chemical Education, JChemEd.chem.wisc.edu, Vol. 78, No. 11, Nov. 2001		
JX-41	79			Chien, Transnasal Systemic Medications, Fundamentals, Developmental Concepts and Biomedical Assessments, 1985 (Chien I)		
JX-42	80			Chein, Nasal Systemic Drug Delivery, 1989 (Chien II)		
JX-43	99			Guidance for Industry: Q1B Photostability Testing of New Drug Substances and Products, November 1996, ICH (Guidance)		
JX-44	100			Experimental and computational approaches to estimate solubility and permeability in drug discovery and development settings," Lipinski et. al., Advanced Drug Delivery Reviews 23 (1997) 3-25) (Lipinski)		

JX	DX	PX	Date	Description	Beg Bates No.	End Bates No.
JX-45	105			Tfelt-Hansen, Efficacy and adverse events of subcutaneous, oral, and intranasal Sumatriptan used for migraine treatment: a systematic review based on number needed to treat, Department of Neurology, Bispebjerg Hospital, Copenhagen, Denmark 1998	ZOMIG00116211	ZOMIG00116217
JX-46		68	1997	Article: Seaber, E., et al., The Absolute Bioavailability and Metabolic Disposition of the Novel Antimigraine Compound Zolmitriiptan (311C90), British Journal Clinical Pharamacology, Vol. 43:579-587 (1997)	ZOMIG00116192	ZOMIG00116200
JX-47		135	1995	Book: Carstensen, J., Drug Stability: Principles and Practices, 2nd Ed., Revised and Expanded, Marcel Decker, Inc.: New York (1995)		

PX	Date	Description	Beg Bates No.	End Bates No.	Objections
PX-1	6/15/2004	Patent: U.S. Patent No. 6,750,237 B1, Issued to Dearn, et al.	ZOMIG00115627	ZOMIG00115630	No objection
PX-2	5/22/2007	Patent: U.S. Patent No. 7,220,767 B2, Issued to Dearn, et al.	ZOMIG00115623	ZOMIG00115626	No Objection
PX-3		Patent: File History of U.S. Patent No. 6,750,237	IMPAX-AZ00000001	IMPAX-AZ00000394	Hearsay as to any statement not made by the Examiner
PX-4		Patent: File History of U.S. Patent No. 7,220,767	IMPAX-AZ00000395	IMPAX-AZ00000564	Hearsay as to any statement not made by the Examiner
PX-5	9/3/2000	Patent: UK Patent Application No. 99/28578, Issued to Astrazeneca UK Limited			Authentication; not produced in discovery
PX-6	6/13/2014	Correspondence: June 13, 2014 Letter Sabo to Astrazeneca AB and Astra Zeneca Pharaceuticals LP re Notice of Certification Under 21 U.S.C.§ 355(j)(2)(B) (§505(j)(2)(B) of Federal Food, Drug, and Cosmetic Act) and 21 C.F.R. § 314.95 Lannett Holding Inc.'s Zolmitriptan Nasal Spray, 5 mg/spray ANDA 206350	ZOMIG00125555	ZOMIG00125587	relevance; hearsay
PX-7	11/11/2005	Patent: Declaration Under 37 C.F.R. § 1.132 of Dr. Ed Cahill with Exhibit A in Patent Application No. 10/854959	ZOMIG00125588	ZOMIG00125591	hearsay; incomplete (Rule 106)
PX-8	1/31/2012	[redacted]	ZOMIG00000359	ZOMIG00000636	authentication; foundation; Rule 403; Hearsay
PX-9	12/16/1999	Patent: International Patent Application No. WO 99/064044, Issued to Marquess, et al.	ZOMIG00117592	ZOMIG00117781	
PX-10	12/4/2001	Patent: U.S. Patent No. 6,326,401 B1, Issued to Chauveau, et al.	ZOMIG00116736	ZOMIG00116742	
PX-11	2/5/2002	Patent: U.S. Patent No. 6,344,449 B1, Issued to Rudolf, et al.	ZOMIG00116743	ZOMIG00116872	
PX-12	3/12/1985	Patent: U.S. Patent No. 4,504,470, Issued to Uda, et al.	ZOMIG00116611	ZOMIG00116619	
PX-13	1/9/1996	Patent: U.S. Patent No. 5,482,931, Issued to Harris, et al.	ZOMIG00116687	ZOMIG00116693	
PX-14	6/6/1991	Patent: European Patent Application No. EP 06/36623 A1, Issued to Robertson	ZOMIG00116476	ZOMIG00116516	
PX-15	1/22/1998	Patent: International Patent Application No. WO 98/02187, Issued to Penkler, et al.	ZOMIG00116326	ZOMIG00116376	
PX-16	8/22/1996	Article: Barrow, A., et al., The Absorption, Pharmacodynamics, Metabolism and Excretion of C-Sumatriptan Following Intransaal Administration to the Beagle Dog, Biopharmaceutics & Drug Disposition, Vol. 18:443-458 (1997)	ZOMIG00116441	ZOMIG00116456	
PX-17	5/16/1991	Patent: Japanese Patent No. JP 03/115219, Issued to Yano (English Translation)	ZOMIG00116591	ZOMIG00116603	
PX-18	9/23/1921	Article: McIlvaine, T.C., A Buffer Solution for Colorimetric Comparison, The Journal of Biological Chemistry, Vol. 49:183-186 (1921)	ZOMIG00116573	ZOMIG00116576	
PX-19	1995	Book: Gennaro, A., Remington: The Science and Practice of Pharmacy, 19th Ed., Mack Publishing Co.: Easton, PA (1995)	ZOMIG00128792	ZOMIG00128805	Incomplete (Rule 102)
PX-20		Image: Zolmitriptan	LAN_ZOLM00000001	LAN_ZOLM00000001	foundation; relevance; hearsay
PX-21	11/7/2013	Report: November 7, 2013, Zolmitriptan Nasal Spray, 5mg 2.3.P Quality Overal Summary-Drug Product, by Lannett Holdings, Inc.	LAN_ZOLM00000091	LAN_ZOLM00000115	Incomplete (Rule 102); Hearsay; authentication
PX-22	11/1/2013	Report: November 1, 2013, Zolmitriptan Nasal Spray, 5mg 2.3.S Quality Overal Summary-Drug Substance, by Lannett Holdings, Inc.	LAN_ZOLM00000116	LAN_ZOLM00000127	Incomplete (Rule 102); Hearsay; authentication
PX-23	11/1/2013	Report: November 1, 2013, Pharmaceutical Development Report on Zomitriptan Nasal Spray, 5mg, Report No. DR09-ZM-06, by Summit Biosciences Inc.	LAN_ZOLM00000163	LAN_ZOLM00000245	Incomplete (Rule 102); Hearsay; authentication
PX-24		Report: Zolmitriptan Nasal Spray, 5mg, 1.12.12 Comparison of Generic Drug and Reference Listed Drug, by Lannett Holdings, Inc.	LAN_ZOLM00000252	LAN_ZOLM00000252	Incomplete (Rule 102); Hearsay; authentication; relevance
PX-25		Report: Zolmitriptan Nasal Spray, 5mg, 3.2.P.1 Description and Composition of the Drug Product, by Lannett Holdings, Inc.	LAN_ZOLM00000364	LAN_ZOLM00000364	Incomplete (Rule 102); Hearsay; authentication; relevance
PX-26	9/12/2013	Report: September 12, 2013, Zolmitriptan Nasal Spray 5mg, 3.2.P.8.3 Stability Data, by Lannett Holdings, Inc.	LAN_ZOLM00001399	LAN_ZOLM00001414	Incomplete (Rule 102); Hearsay; authentication; relevance
PX-27	2/3/2010	[redacted]	LAN_ZOLM00005183	LAN_ZOLM00005203	Incomplete (Rule 102); Hearsay; authentication; relevance

PX	Date	Description	Beg Bates No.	End Bates No.	Objections
PX-28		Report: Zomig (Zolmitriptan) Nasal Spray 2.5mg/5mg Pediatric Indication (Pediatric Patients 12 Years and Older), by Impax Pharmaceuticals	ZOMIG00003336	ZOMIG00003375	authentication; hearsay; relevance; foundation; improper expert opinion
PX-29		Report: Zomig (Zolmitriptan) Nasal Spray 2.5mg/5mg Module 1: Migraine Background, by Impax Pharmaceuticals	ZOMIG00003376	ZOMIG00003413	authentication; hearsay; foundation; relevance; improper expert opinion
PX-30		Report: Zomig (Zolmitriptan) Nasal Spray 2.5mg/5mg Module 2: Anatomy & Physiology, by Impax Pharmaceuticals	ZOMIG00003414	ZOMIG00003477	authentication; hearsay; relevance; foundation; improper expert opinion
PX-31		Report: Zomig (Zolmitriptan) Nasal Spray 2.5mg/5mg Module 3: Classification, Pathophysiology, and Diagnosis, by Impax Pharmaceuticals	ZOMIG00003478	ZOMIG00003541	authentication; hearsay; relevance; foundation; improper expert opinion
PX-32		Report: Zomig (Zolmitriptan) Nasal Spray 2.5mg/5mg Module 4:Treatment & Prevention, by Impax Pharmaceuticals	ZOMIG00003542	ZOMIG00003607	authentication; hearsay; relevance; foundation; improper expert opinion
PX-33		Report: Zomig (Zolmitriptan) Nasal Spray 2.5mg/5mg Module 5:Understanding the Customer, by Impax Pharmaceuticals	ZOMIG00003608	ZOMIG00003647	authentication; hearsay; relevance; foundation; improper expert opinion
PX-34	2012	Image: Ads of Zomig Zomitriptan Nasal Spray 2.5mg/5mg, by Impax Pharmaceuticals	ZOMIG00003648	ZOMIG00003654	authentication; hearsay; relevance; foundation; improper expert opinion
PX-35		Image: Ads of Zomig Zomitriptan Nasal Spray 2.5mg/5mg, by Impax Pharmaceuticals	ZOMIG00003665	ZOMIG00003674	authentication; hearsay; relevance; foundation; improper expert opinion
PX-36		Report: Full Prescribing Information of Zomig Zomitriptan Nasal Spray 2.5mg/5mg, Impax Pharmaceuticals	ZOMIG00003702	ZOMIG00003710	authentication; hearsay; relevance; foundation; improper expert opinion
PX-37		Image: Ads of Zomig Zomitriptan Nasal Spray 2.5mg/5mg, by Impax Pharmaceuticals	ZOMIG00003711	ZOMIG00003717	authentication; hearsay; relevance; foundation; improper expert opinion
PX-38		Presentation: ZOMIG Nasal Spray Training Deck	ZOMIG00003727	ZOMIG00003812	authentication; hearsay; relevance; foundation; improper expert opinion
PX-39		Images: Screenshots of Zomig Zolmitriptan Nasal Spray Every Minute Counts Training	ZOMIG00003813	ZOMIG00003972	authentication; hearsay; relevance; foundation; improper expert opinion
PX-40	12/8/1998	Correspondence: December 8, 1998 Letter from Shatwell to Oldham re 'Zomig' Nasal Spray Stability	ZOMIG00006832	ZOMIG00006833	authentication; hearsay; relevance; foundation; improper expert opinion
PX-41		Spreadsheet: 2003-2012 NPA	ZOMIG00024651	ZOMIG00024651	authentication; hearsay; relevance; foundation; improper summary
PX-42		Spreadsheet: TRx, NRx, EUTRx, Sales$ for March 2009 to March 2015	ZOMIG00024652	ZOMIG00024652	authentication; hearsay; relevance; foundation; improper summary
PX-43	7/11/1997	Report: July 11, 1997, A Study to Determine the Influence of pH on the Absorption of an Intranasal Solution of the Novel Antimigraine Drug Zomitriptan [311C90, ZOMIG], and to Examine the Pharmacokinetics of a 2.5mg Dose, Both as an Intranasal and Tablet Formulation, in Healthy Volunteers, by Zeneca Pharmaceuticals Medical Research and Communications Group	ZOMIG00025277	ZOMIG00025625	authentication; hearsay; relevance; foundation; improper expert opinion
PX-44		Report: Pharmaceutical Development	ZOMIG00058703	ZOMIG00058754	authentication; hearsay; relevance; foundation; improper expert opinion
PX-45		Report: Zolmitriptan: Micronucleus Test in the Rat: Oral Administration of Nasal Spray Formulation and a Degraded Nasal Formulation, Study Number TQR/3080	ZOMIG00115557	ZOMIG00115584	authentication; hearsay; relevance; foundation; improper expert opinion; best evidence
PX-46		Website: UC Davis Chem Wiki 3.4: Avogadro's Number and the Mole	ZOMIG00115722	ZOMIG00115734	authentication; hearsay; relevance; improper expert opinion
PX-47	3/19/1992	Article: Park, G., et al., Acycolvir Permeation Enhancement Across Intestinal and Nasal Mucosae by Bile Salt-Acylcarnitine Mixed Micelles, Pharmaceutical Research, Vol. 9, No. 10:1262-1267 (1992)	ZOMIG00115735	ZOMIG00115740	

PX	Date	Description	Beg Bates No.	End Bates No.	Objections
PX-48		Website: AstraZeneca's Intranasal Form of Zomig Answers Pressing Need in Migraine, Available at: http://www.thepharmaletter.com/article/astrazeneca-s-intranasal-form-of-zomig-answers-pressing-need-in-migraine	ZOMIG00115741	ZOMIG00115742	authentication; hearsay; relevance; foundation; improper expert opinion
PX-49	10/3/2001	Article: Clement, E.M., Simultaneous Measurement of Zolmitriptan and Its Major Metabolites N-desmethylzolmitriptan and zolmitriptan N-oxide in Human Plasma by High-Performance Liquid Chromatography with Coulometric Detection, Journal of Chromatography B, Vol. 766:339-343 (2002)	ZOMIG00115777	ZOMIG00115781	authentication; hearsay; relevance; foundation; improper expert opinion
PX-50	2/18/1998	Article: Dahlof, CGH., et al., How does Sumatriptan Nasal Spray Perform in Clinical Practice?, Cephalalgia Vol. 18:278-282 (1998)	ZOMIG00115782	ZOMIG00115786	
PX-51	1997	Article: Dixon, R., and Warrrander, A., The Clinical Pharmacokinetics of Zomitriptan, Cephalalgia, Vol. 17 Supp. 18:15-20 (1997)	ZOMIG00115792	ZOMIG00115797	
PX-52	2/25/2005	Article: Charlesworth, B. and Dowson, A., Review of Zolmitriptan and its Clinical Applications in Migraine, Expert Opinion on Pharmacotherapy, Vol. 3:7:993-1005	ZOMIG00115798	ZOMIG00115811	authentication; hearsay; relevance; foundation; improper expert opinion
PX-53	3/30/1995	Article: Glen, R., et al., Computer-Aided Design and Synthesis of 5-Substituted Tryptamines and Their Pharmacology at the 5-HT1D Receptor: Discovery of Compounds with Potential Anti-Migraine Properties, Journal of Medical Chemistry, Vol. 38:3566-3580 (1995)	ZOMIG00115829	ZOMIG00115843	
PX-54	6/25/2009	Article: Hedlund, C., Zolmitriptan Nasal Spray in the Acute Treatment of Cluster Headache: A Meta-Analysis of Two Studies, Headache, Vol. 49:1315-1323, (2009)	ZOMIG00115844	ZOMIG00115852	authentication; hearsay; relevance; foundation; improper expert opinion
PX-55	2/1/2012	Article: Press Release-Impax Pharmaceuticals Licenses Exclusive US Commercialization Rights to Zomig (zomitriptan) from AstraZeneca, Available at http://www.reuters.com/article/idUS143320+01-Feb-2012+BW20120201	ZOMIG00115854	ZOMIG00115857	authentication; hearsay; relevance; foundation; improper expert opinion
PX-56	11/4/2014	Article: Press Release-Impax's Third Quarter 2014 Revenues Increased 19% to $158 Million, Available at http://investors.impaxiabs.com/Media-Center/Press-Releases/Press-Release-Details/2014/Impaxs-Third-Quarter-2014-Revenues-Increased-19-to-158-Milli…	ZOMIG00115858	ZOMIG00115870	authentication; hearsay; relevance; improper expert opinion
PX-57	2/24/2015	Article: Press Release-Impax Revenues Increased 30% to $131 Million in Fourth Quarter 2014, Available at: http://investors.impaxiabs.com/Media-Center/Press-Releases/Press-Release-Details/2015/Impax-Revenues-Increased-30-to-131-Million-in-Fourth-Quarter-...	ZOMIG00115871	ZOMIG00115885	authentication; hearsay; relevance; improper expert opinion
PX-58	1999	Article: Lipton, R. and Stewart, W., Acute Migraine Therapy: Do Doctors Understand What PAtients with Migraine Want From Therapy?, Headache, Vol. 39 Supp:S20-S26 (1999)	ZOMIG00116052	ZOMIG00116058	authentication; hearsay; relevance; improper expert opinion
PX-59	1997	Article: Martin, G.R., et al., Receptor Specificity and Trigemino-Vascular Inhibitory Actions of a Novel 5-HT1B/1D Receptor Partial Agonist, 311C90 (zomitriptan), British Journal of Pharmacology, Vol. 121:157-164 (1997)	ZOMIG00116059	ZOMIG00116066	
PX-60	1997	Article: Martin, G.R., Pre-Clinical Pharmacology of Zomitriptan (Zomig; Formerly 311C90), a Centrally and Peripherally Acting 5HT1B/1D Agonist for Migraine, Cephalalgia, Vol. 18 Supp:4-14 (1997)	ZOMIG00116067	ZOMIG00116077	
PX-61		Spreadsheet: TRx, NRx, EUTRx, $ for Oct 2009 to Sept 2015	ZOMIG00116092	ZOMIG00116092	authentication; hearsay; relevance; foundation; improper summary
PX-62	2002	Article: Nairn, K., et al., Evaluation of the Effect of Xylometazoline on the Absorption of Zolmitriptan Nasal Spray, Clinical Drug Invest, Vol. 20(10): 703-707 (2002)	ZOMIG00116093	ZOMIG00116097	authentication; hearsay; relevance; foundation; improper expert opinion
PX-63	2009	Article: Kalanuria, A.A., and Peterlin, B.L., A Review of the Pharmacokinetics, Pharmacodynamics and Efficacy of Zolmitriptan in the Actue Abortive Treatment of Migraine, Clinical Medicine: Therapeutics, Vol. 1:397-413 (2009)	ZOMIG00116111	ZOMIG00116127	authentication; hearsay; relevance; foundation; improper expert opinion
PX-64	2004	Article: Rapoport, A., et al., Future Drug Zolmitriptan (Zomig), Expert Rev. Neurotherapeutics, Vol. 4(1): 33-41 (2004)	ZOMIG00116128	ZOMIG00116136	authentication; hearsay; relevance; foundation; improper expert opinion
PX-65	8/28/2007	Article: Rapoport, A., et al., Zolmitriptan Nasal Spray in the Actue Treatment of Cluster Headache, Neurology, Vol. 69: 821-826 (2007)	ZOMIG00116137	ZOMIG00116142	authentication; hearsay; relevance; foundation; improper expert opinion

PX	Date	Description	Beg Bates No.	End Bates No.	Objections
PX-66	1995	Book: Gennaro, A., Remington: The Science and Practice of Pharmacy, 19th Ed., Mack Publishing Co.: Easton, PA (1995)	ZOMIG00116144	ZOMIG00116171	incomplete
PX-67		Website: Sales of Zomig Nasal Spray Increase 54%, Available at: http://www.oindpnews.com/2014/11//sales-of-zomig-nasal-spray-increase-54	ZOMIG00116172	ZOMIG00116173	authentication; hearsay; relevance; improper expert opinion; improper summary
PX-68	1997	Article: Seaber, E., et al., The Absolute Bioavailability and Metabolic Disposition of the Novel Antimigraine Compound Zolmitriiptan (311C90), British Journal Clinical Pharamacology, Vol. 43:579-587 (1997)	ZOMIG00116192	ZOMIG00116200	No objection
PX-69	2013	Article: Tepper, S., et al., Intranasal Zolmitriptan for the Treatment of Acute Migraine, Headach, Vol. 53, No. S2:62-71 (2013)	ZOMIG00116201	ZOMIG00116210	authentication; hearsay; relevance; improper expert opinion
PX-70	1/29/1998	Article: Tfelt-Hansen, P., Efficacy and Adverse Events of Subcutaneous, Oral, and Intranasal Sumatriptan Used for Migraine Treatment: A Systematic Review Based on Number Needed to Treat, Cephalalgia, Vol. 18:532-538 (1998)	ZOMIG00116211	ZOMIG00116217	No objection
PX-71	2000	Article: Tfelt-Hansen, P., et al., Triptans in Migraine, Drugs, Vol. 60, No. 6:1259-1287(2000)	ZOMIG00116218	ZOMIG00116248	authentication; hearsay; relevance; foundation; improper expert opinion
PX-72	2006	Article: Uemura, N., et al., Bioequivalence and Rapid Absorption of Zolmitriptan Nasal Spray Compared with Oral Tablets in Healthy Japanese Subjects, Clinical Drug Invest. Vol. 25(3):199-208 (2006)	ZOMIG00116249	ZOMIG00116258	authentication; hearsay; relevance; foundation; improper expert opinion
PX-73	1980	Article: Van de Donk, H.J.M., et al., The Influence of the pH and Osmotic Pressure Upon Tracheal Ciliary Beat Frequency as Determined with a New Photo-Electric Registration Device, Rhinology, Vol. 18:93-104 (1980)	ZOMIG00116259	ZOMIG00116272	relevance
PX-74	2002	Article: Yates, R., et. al., Preliminary Studies of the Pharmacokinetics and Tolerability of Zolmitriptan Nasal Spray in Healthy Volunteers, Journal of Clinical Pharmacology, Vol. 42:1237-1243 (2002)	ZOMIG00116277	ZOMIG00116283	authentication; hearsay; relevance; foundation; improper expert opinion
PX-75		Spreadsheet: Program Highlights for Client Impax, by MM Health Solutions	ZOMIG00116284	ZOMIG00116284	authentication; hearsay; relevance; foundation; improper summary
PX-76		Spreadsheet: Program Highlights for Client Impax, by MM Health Solutions	ZOMIG00116285	ZOMIG00116285	authentication; hearsay; relevance; foundation; improper summary
PX-77	Aug-04	Report: 'Zomig' Nasal Spray Clinical Product Summary, Zomig Nasal Spray, by Dahlof and AstraZeneca Neuroscience (8/2004)	ZOMIG00116286	ZOMIG00116325	authentication; hearsay; relevance; foundation; improper expert opinion; improper summary
PX-78	2000	Book: Skoog, D., et al., Analytical Chemistry, 7th Ed., Saunders College Publishing (2000)	ZOMIG00117782	ZOMIG00117861	authentication; hearsay; relevance; improper expert opinion
PX-79	1996	Book: Skoog, D., et al., Fundamentals of Analytical Chemistry, 7th Ed., Thomson Learning, Inc. (1996)	ZOMIG00117862	ZOMIG00117913	authentication; hearsay; relevance; improper expert opinion
PX-80	2008	Book: Lemke, T., et al., Foye's Principles of Medicinal Chemistry, 6th Ed., Lippincott Williams & Wilkins (2008)	ZOMIG00117914	ZOMIG00118038	authentication; hearsay; relevance; improper expert opinion
PX-81	2002	Book: Yoshioka, S. and Stella, V., Stability of Drugs and Dosage Forms, Kluwer Academic Publishers (2002)	ZOMIG00120593	ZOMIG00120866	authentication; hearsay; relevance; improper expert opinion
PX-82		Report: Zecuity-Sumatriptan Succinate Patch, Extended Release, Electrically Controlled, by NuPathe Inc.	ZOMIG00121562	ZOMIG00121592	authentication; hearsay; relevance
PX-83		Report: Zomig-Zolmitriptan Spray, Metered, by Impax Specialty Pharma	ZOMIG00121593	ZOMIG00121621	authentication; hearsay; relevance; improper expert opinion
PX-84		Report: Zomig-Zomitriptan Tablet, Zomig ZMT-Zolmitriptan Tablet, Orally Disintegrating, by Impax Laboratories, Inc.	ZOMIG00121622	ZOMIG00121631	authentication; hearsay; relevance; foundation; improper expert opinion
PX-85	7/28/2015	Declaration of Sveinbjorn Gizurarson, Ph.D. in Lannett Holdings, Inc. v. Astrazenca AB of U.S. Patent No. 6,750,237 to Dearn et al.	ZOMIG00122200	ZOMIG00122250	hearsay; improper expert opinion
PX-86	7/28/2015	Declaration of Sveinbjorn Gizurarson, Ph.D. in Lannett Holdings, Inc. v. Astrazenca AB of U.S. Patent No. 7,220,767 to Dearn et al.	ZOMIG00122251	ZOMIG00122302	hearsay; relevance; incomplete

PX	Date	Description	Beg Bates No.	End Bates No.	Objections
PX-87	1995	Book: Gennaro, A., Remington: The Science and Practice of Pharmacy, 19th Ed., Mack Publishing Co.: Easton, PA (1995)	ZOMIG00122779	ZOMIG00122802	incomplete Rule (102)
PX-88	9/26/1996	Patent: International Patent Application No. WO 96/29074, Issued to Johnson, et al.	ZOMIG00123517	ZOMIG00123575	No objection
PX-89	5/16/1991	Patent: Japanese Patent No. JP 03/115219, Issued to Yano (with English Translation)	ZOMIG00123661	ZOMIG00123678	No objection
PX-90	8/19/2002	Patent: Assignment of Assignors Interest Details for 12995-425	ZOMIG00124117	ZOMIG00124118	authenticity; hearsay; incomplete; foundation
PX-91	10/14/2014	Patent: Patent Assignment, Impax Laboratories, Inc. v. Lannett Holdings, Inc., et al., Case No. 14-cv-984, D.I. No. 13-1, October 14, 2014	ZOMIG00124121	ZOMIG00124124	authenticity; hearsay; incomplete; foundation
PX-92	10/14/2014	Patent: Patent Assignment, Impax Laboratories, Inc. v. Lannett Holdings, Inc., et al., Case No. 14-cv-984, D.I. No. 13-1, October 14, 2014	ZOMIG00124125	ZOMIG00124128	authenticity; hearsay; incomplete; foundation
PX-93	12/10/2014	Pleadings: Memorandum Order, Impax Laboratories, Inc. v. Lannett Holdings, Inc., et al., Case No. 14-cv-984, D.I. No. 33, December 10, 2014	ZOMIG00124129	ZOMIG00124131	relevance
PX-94	5/26/2000	Research: Department of Health and Human Services Food and Drug Administration 21 CFR Part 200, D.I. No. 96N-0048, Sterility Requirement for Aqueous-Based Drug Products for Oral Inhalation, May 26, 2000	ZOMIG00124850	ZOMIG00124857	hearsay; relevance; incomplete
PX-95	12/31/2015	Financial: 12/31/2015 Impax Laboratories, Inc. Gross-toNet Sales & Gross Profit			authentication; hearsay; foundation; relevance; foundation; improper summary
PX-96	3/31/2016	Presentation: 3/31/2016 Zomig Nasal Spray Physician ATU Wave 6 by AlphaImpact Rx	ZOMIG00125414	ZOMIG00125506	authentication; hearsay; foundation; relevance; foundation; improper summary
PX-97	5/4/2010	Report: 5/4/2010 Developmental Report, Zolmitriptan Nasal Spray, 50 mg/mL Formulation Report (DR09-ZT-00) by Summit Biosciences Inc.	SUMMIT00006497	SUMMIT00006543	authentication; hearsay; relevance; foundation; incomplete; best evidence
PX-98		Spreadsheet: Sumitriptan Nasal Spray USP (5 and 20 mg) Components	SUMMIT00006543	SUMMIT00006543	authentication; hearsay; relevance; foundation; incomplete; best evidence
PX-99	10/8/2012	Correspondence: 10/8/2012 Letter K. Sims to G. Wei re Enclosing Zolmitriptan Samples for Exposure	SUMMIT00006547	SUMMIT00006547	authentication; hearsay; relevance; foundation; incomplete; best evidence
PX-100	10/16/2012	Report: 10/16/2012 Zolmitriptan Nasal Spray Teleconference Agenda	SUMMIT00006035	SUMMIT00006035	authentication; hearsay; relevance; foundation
PX-101		Report: Zolmitriptan 2.5 mg Task List	SUMMIT00041230	SUMMIT00041230	authentication; hearsay; relevance; incomplete
PX-102	11/7/2013	Report: 11/7/2013 2.3.P Quality Overall Summary-Drug Product by Lannett Regulatory Affairs	SUMMIT00000368	SUMMIT00000392	authentication; hearsay; relevance; foundation
PX-103	10/5/2012	Correspondence: 10/5/2012 Letter J. Medley to G. Plucinski re Determination of Osmolarity and Osmolaity in Zolmitriptan Formulation	SUMMIT00032070	SUMMIT00032074	authentication; hearsay; relevance; foundation
PX-104	1/16/2013	Report: 1/16/2013 Zolmitriptan Formulation Comparison by Summit Biosciences Inc.	SUMMIT00006770	SUMMIT00006772	authentication; hearsay; relevance; foundation
PX-105	11/1/2013	Report: 11/1/2013 Pharmaceutical Development Report, Zomig Nasal Spray, 5 mg (DR09-ZM-06) by Summit Bioscences, Inc.	SUMMIT00022435	SUMMIT00022517	authentication; hearsay; relevance; foundation
PX-106	June 2015	Report: Prescribing Information of ZOLMITRIPTAN nasal spray, 5 mg	LAN_ZOLM0005629	LAN_ZOLM0005653	authentication; hearsay; relevance; foundation; incomplete
PX-107	11/1/2013	Report: 11/1/2013 Pharmaceutical Development Report, Zomig Nasal Spray, 5 mg (DR09-ZM-06) by Summit Bioscences, Inc.	LAN ZOLM00000164	LAN ZOLM00000245	authentication; hearsay; relevance; foundation; incomplete
PX-108		Report: 3.2.P.5.6 Justification of Specifications by Lannett Holdings, Inc.	LAN_ZOLM0006452	LAN_ZOLM0006455	authentication; hearsay; relevance; incomplete;
PX-109	8/31/2015	Report: 8/31/2015 3.2.P.8.3 Stability Data by Lannett Holdings, Inc.	LAN_ZOLM0006776	LAN_ZOLM0006780	authentication; hearsay; relevance; incomplete

PX	Date	Description	Beg Bates No.	End Bates No.	Objections
PX-110		Report: 3.2.S.1 General Information by Lannett Holdings, Inc.	LAN_ZOLM00001562	LAN_ZOLM00001564	authentication; hearsay; relevance; incomplete
PX-111	9/2/2016	Report: 9/2/2015 Material Specification No. MS9021 by Summit Biosciences Inc.	LAN_ZOLM0006249	LAN_ZOLM0006253	authentication; hearsay; relevance; incomplete
PX-112	1/17/2013	Report: 1/17/2013 Risk Assessment: Zolmitriptan Enantiomeric Purity Testing by Summit Biosciences Inc.	LAN_ZOLM0006445	LAN_ZOLM0006451	authentication; hearsay; relevance; incomplete
PX-113		Report: 3.2.P.7.1 Summary of Container/Closure System by Lannett Holdings, Inc.	LAN_ZOLM0006612	LAN_ZOLM0006616	authentication; hearsay; relevance; incomplete
PX-114	9/3/2015	Report: 9/3/2015 Material Specification No. MS9021 by Summit Biosciences Inc.	LAN_ZOLM0006794	LAN_ZOLM0006795	authentication; hearsay; relevance; incomplete
PX-115	5/19/2011	Report: 5/19/2011 USP Certificate of Analysis for Zolmitriptan USP (LOT F0K147)	LAN_ZOLM0006838	LAN_ZOLM0006839	authentication; hearsay; relevance; incomplete
PX-116	9/3/2015	Report: 9/3/2015 3.2.S.4.5 Justification of Specification by Lannett Holdings, Inc.	LAN_ZOLM0006894	LAN_ZOLM0006895	authentication; hearsay; relevance; incomplete
PX-117	11/10/2015	Report: 11/10/2015 Application for Zolmitriptan Nasal Spray (ANDA No. 206350)	LAN_ZOLM0006904	LAN_ZOLM0006909	authentication; hearsay; relevance; incomplete
PX-118	10/30/2015	Report: 10/30/2015 Method Verification Report of Zolmitriptan Drug Substance (PLIVA API), Report No. R15-088 by S. Spera	LAN_ZOLM0007154	LAN_ZOLM0007184	authentication; hearsay; relevance; incomplete
PX-119	10/30/2015	Report: 10/30/2015 Quality Control, PA Site, Method Validation Report of Zolmitriptan Drug Substance (Pliva API), Report No. R15-090 by C. Marks	LAN_ZOLM0007228	LAN_ZOLM0007266	authentication; hearsay; relevance; incomplete
PX-120	9/23/2015	Pleading: D.I. 50, Joint Appendix in Support of the Parties' Joint Claim Construction Brief (1:14-cv-00984-RGA)			relevance; hearsay
PX-121	11/16/2015	Pleading: D.I. 59, Transcript of Markman Hearing Before the Honorable Richard G. Andrews (1:14-cv-00984-RGA)			relevance; hearsay
PX-122	12/1/2015	Pleading: D.I. 60, Memorandum Opinion (1:14-cv-00984-RGA)			relevance; hearsay
PX-123	12/8/2015	Pleading: D.I. 64, Claim Construction Order (1:14-cv-00984-RGA)			relevance; hearsay
PX-124	1/29/2016	Transcript: Deposition of K. Stephens			relevance; hearsay
PX-125		Report: Exhibit A: Curriculum Vitae of H. Smyth			relevance; hearsay
PX-126		Report: Exhibit B: Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations			relevance; hearsay
PX-127		Website: ChemWiki: The Dynamic Chemistry Hypertext Available at: http://chemwiki.ucdavis.edu/	ZOMIG00125554	ZOMIG00125554	authentication; hearsay; relevance; foundation; improper expert opinion
PX-128		Website: IUPAC Gold Book Definition of Chemical Equilbrium, Available at: http://goldbook.iupac.org/C01023.html	ZOMIG00125514	ZOMIG00125515	authentication; hearsay; relevance; foundation; improper expert opinion
PX-129		Report: Highlights of Prescribing Information of Astelin (Azelastine Hydrochloride) Nasal Spray, by Meda Pharmaceuticals, Inc.	ZOMIG00125599	ZOMIG00125619	authentication; hearsay; relevance; foundation; improper expert opinion
PX-130	1988	Book: Aulton, M., Pharmaceutics: The Science of Dosage Form Design, 1st Ed., Churchill Livingstone: New York (1988)	ZOMIG00125621	ZOMIG00125641	authentication; hearsay; relevance; foundation; improper expert opinion
PX-131	2007	Book: Aulton, M., Aulton's Pharmaceutics: The Design and Manufacture of Medicines, 3rd Ed., Churchill Livingstone: New York (2007)	ZOMIG00125642	ZOMIG00125675	authentication; hearsay; relevance; foundation; improper expert opinion
PX-132	2002	Book: Banker, G. and Rhodes, C., Modern Pharmaceutics, 4th Ed., Revised and Expanded, Marcel Dekker, Inc.: New York (2002)	ZOMIG00125681	ZOMIG00126505	authentication; hearsay; relevance; foundation; improper expert opinion
PX-133	1997	Article: Bjorkman, S., et al., Pharmacokinetics of Midazolam Given as an Intranasal Spray to Adult Surgical Patients, British Journal of Anaesthesia, Vol. 79:575-580 (1997)	ZOMIG00126528	ZOMIG00126533	Relevance
PX-134	1994	Article: Boulton, D., et al., The Stability of an Enalapril Maleate Oral Solution Prepared from Tablets, Australian Journal of Hospiral Pharmacy, Vol. 24, Issue 2:151-156 (1994)			Relevance

PX	Date	Description	Beg Bates No.	End Bates No.	Objections
PX-135	1995	Book: Carstensen, J., Drug Stability: Principles and Practices, 2nd Ed., Revised and Expanded, Marcel Decker, Inc.: New York (1995)			No objection
PX-136	3/4/2008	Article: Christrup, L., et al., Pharmacokinetics, Efficacy, and Tolerability of Fentanyl Following Intranasal Versus Intravenous Administration in Adults Undergoing Third-Molar Extraction: A Randomized, Double-Blind, Double-Dummy, Two-Way, Crossover Study, Clinical Therapeutics, Vol. 30, Issue 3:469-481 (2008)	ZOMIG00126554	ZOMIG00126566	authentication; hearsay; relevance; foundation; improper expert opinion
PX-137	2003	Article: Coda, B., et al., Pharmacokinetics and Bioavilability of Single-Does Intranasal Hydromorphone Hydrochloride in Healthy Volunteers, Anesth. Analg., Vol. 97:117-123 (2003)	ZOMIG00126567	ZOMIG00126573	authentication; hearsay; relevance; foundation; improper expert opinion
PX-138	1986	Book: Connors, K., et al., Chemical Stability of Pharmaceuticals: A Handbook for Pharmacists, 2nd Ed., John Wiley & Sons, Inc.: New York (1986)			
PX-139	Mar-64	Article: Fabricant, N., The pH of the Throat, Nose, and Ear, The Eye, Ear, Nose and Throat Monthly, Vol. 43, Issue 3:60, 76 (1964)			
PX-140	2009	Book: Gibson, M., Pharmaceutical Preformulation and Formulation: A Practical Guide from Candidate Drug Selection to Commercial Dosage Form, 2nd Ed., Informa Healthcare USA, Inc.: New York (2009)	ZOMIG00126658	ZOMIG00127216	authentication; hearsay; relevance; foundation; improper expert opinion
PX-141	2/7/2015	Article: Gizurarson, S., The Effect of Cilia and the Mucociliary Clearance on Successful Drug Delivery, Biol. Pharm. Bull., Vol. 38, Issue 4:497-506 (2015)	ZOMIG00127217	ZOMIG00127226	authentication; hearsay; relevance; improper expert opinion
PX-142	1986	Article: Gupta, V., et al., Stability of Hydralazine Hydrochloride in Aqueous Vehicles, Journal of Clinical and Hospital Pharmacy, Vol. 11:215-223 (1986)			relevance
PX-143	Nov-12	Report: November 2012 New Medicines Committee Briefing on Fentanyl citrate nasal spray (PecFent®), by S. Heuschkel	ZOMIG00127257	ZOMIG00127268	authentication; hearsay; relevance; foundation; improper expert opinion
PX-144		Report: Galvu Summary of Product Characteristics (Annex I-IV)	ZOMIG00127269	ZOMIG00127369	authentication; hearsay; relevance; improper expert opinion; incomplete (Rule 102); foundation
PX-145	2003	Article: Lim, S., et al., Pharmacokinetics of Nasal Fentanyl, Journal of Pharmacy Practice and Research, Vol. 33, Issue 1:59-64 (2003)	ZOMIG00127409	ZOMIG00127414	authentication; hearsay; relevance; improper expert opinion; foundation
PX-146	7/15/2013	Report: 7/15/2013 Product Monograph of PRLivostin® by Janssen Inc.	ZOMIG00127425	ZOMIG00127446	authentication; hearsay; relevance; improper expert opinion; fundation
PX-147	2000	Article: Martin, G., The Pharmacology of Zolmitriptan, Monogr. Clin. Neurosci., Vol. 17: 110-115 (2000)	ZOMIG00127447	ZOMIG00127453	authentication; hearsay; relevance; improper expert opinion; foundation
PX-148	February 1995	Article: Nahata, M., et al., Stability of Cisapride in a Liquid Dosage Form at Two Temperatures, The Annals of Pharmacotherapy, Vol. 29:125-126 (1995)			authentication; hearsay; relevance; improper expert opinion; foundation
PX-149	Jan-10	Report: Prescribing Information of Nictrol®NS (nicotine nasal spray)	ZOMIG00127475	ZOMIG00127494	authentication; hearsay; relevance; improper expert opinion; foundation
PX-150	2000	Book: Gennaro, A., Remington: The Science and Practice of Pharmacy Volume 1, 20th Ed., Lippincott Williams & Wilkins: Maryland (2000)	ZOMIG00127739	ZOMIG00128789	authentication; hearsay; relevance; improper expert opinion; foundation
PX-151	1995	Article: Schols-Hendriks, M., et al., Absorption of Clonazepam After Intranasal and Buccal Administration, Br. J. Clin. Pharmac., Vol. 39:449-451 (1995)	ZOMIG00128806	ZOMIG00128008	authentication; hearsay; relevance; improper expert opinion; foundation
PX-152	1995	Article: Schwagmeier, R., et al., Pharmacokinetics of Intranasal Alfentanil, Journal of Clinical Anesthesia, Vol. 7:109-113 (1995)	ZOMIG00128809	ZOMIG00128813	authentication; hearsay; relevance; improper expert opinion; foundation
PX-153	2011	Article: Sheshala, R., et al., Formulation and Optimization of Orally Disintegrating Tablets of Sumatriptan Succinate, Chem. Pharm. Bull., Vol. 59, Issue 8:920-928 (2011)	ZOMIG00128828	ZOMIG00128836	authentication; hearsay; relevance; improper expert opinion; foundation
PX-154	12/5/2008	Report: 12/8/2008 Center for Drug Evaluation and Research: Chemistry Review(s) of Application No. 22382Orig1s000 Sprix™ (ketorolac tromethamine) Nasal Spray by Roxro Pharma, Inc.	ZOMIG00128845	ZOMIG00128884	authentication; hearsay; relevance; improper expert opinion; foundation
PX-155	2015	Article: van der Glas, S. and Hafner, A., Nose, Practical Pharmaceutics, 139-152 (2015)	ZOMIG00126534	ZOMIG00126547	authentication; hearsay; relevance; improper expert opinion; foundation

PX	Date	Description	Beg Bates No.	End Bates No.	Objections
PX-156	Aug-12	Report: Prescribing Information of VERAMYST (fluticasone furoate) Nasal Spray	ZOMIG00129125	ZOMIG00129153	authentication; hearsay; relevance; improper expert opinion
PX-157	2013	Article: Vollbracht, S. and Rapoport, A., The Pipeline in Headache Therapy, CNS Drugs, Vol. 27:717-729 (2013)	ZOMIG00129154	ZOMIG00129166	authentication; hearsay; relevance; improper expert opinion; foundation
PX-158	1999	Article: Wang, W., Instability, Stabilization, and Formulation of Liquid Protein Pharmaceuticals, Vol. 185:129-188 (1999)	ZOMIG00129167	ZOMIG00129226	authentication; hearsay; relevance; improper expert opinion; foundation
PX-159	4/7/2016	Report: 4/7/2016 Public Assessment Report: Scientific Discussion of Xylometazoline HCl Dr. Max 0.5 mg/ml and 1 mg/ml, nasal spray, solution (xylometazoline hydrochloride)	ZOMIG00129227	ZOMIG00129234	authentication; hearsay; relevance; improper expert opinion; foundation
PX-160	6/10/2016	Correspondence: 6/10/2016 Letter D. Hurtukova to Health Care Provider re Voluntary Suspension of the Sale, Marketing, and Distribution of ZECURITY® (sumatriptan iontophoretic transdermal system) Due to Reported Cases of Serious Application Site Reactions	ZOMIG00129263	ZOMIG00129264	authentication; hearsay; relevance; improper expert opinion; foundation
PX-161	5/26/2000	Article: Lake, L., Department of Health and Human Services 21 CFR Part 200 [D.I. No. 96N-0048] RIN 0910-AA88: Sterility Requirement for Aqueous-Based Drug Products for Oral Inhalation, Federal Register, Vol. 65, Issue 103:34082-34089 (2000)	ZOMIG00126621	ZOMIG00126628	authentication; hearsay; relevance; improper expert opinion; foundation
PX-162	6/16/2016	Image: 6/16/2016 Atrovent 250 mcg/2 mL Product Packaging	ZOMIG00125620	ZOMIG00125620	authentication; hearsay; relevance; improper expert opinion; foundation; best evidence
PX-163	6/16/2016	Image: 6/16/2016 Suprecur Product Details	ZOMIG00128888	ZOMIG00128888	authentication; hearsay; relevance; improper expert opinion; best evidenvce; foundation
PX-164	11/14/1995	Patent: U.S. Patent No. 5,466,699, Issued to Robertson, et al.	ZOMIG00128981	ZOMIG00129001	No objection
PX-165	1/26/1999	Patent: U.S. Patent No. 5,863,935, Issued to Robertson, et al.	ZOMIG00129055	ZOMIG00129074	No objection
PX-166	2/6/2001	Patent: U.S. Patent No. 6,184,220 B1, Issued to Turck, et al.			authentication; hearsay; relevance; improper expert opinion; foundation
PX-167	10/19/2012	Correspondence: 10/19/2012 Email G. Plucinski to J. Medley re Ionized Drug Concentrations Made Easy	SUMMIT00047303	SUMMIT00047304	authentication; hearsay; relevance; foundation
PX-168	10/25/2012	Correspondence: 10/25/2012 Email G. Plucinski to J. Medley and T. Palmer re Possible Alternate Zolmitriptan Formulation	SUMMIT00047305	SUMMIT00047306	authentication; hearsay; relevance
PX-169	November 2000	Report: 11/2000 The Complete ZOMIG: A-Z Document, Questions & Messages	ZOMIG00023747	ZOMIG00023795	authentication; hearsay; relevance; improper expert opinion; foundation
PX-170		Report: Pharmacy Clinical Policy Bulletins, Aetna Non-Medicare Prescription Drug Plans, Subject: Anti-Migraine Agents by Aetna	ZOMIG00125592	ZOMIG00125598	authentication; hearsay; relevance; improper expert opinion; foundation
PX-171	1/1/2011	Website: January 1, 2011 Stability Considerations for Biopharmaceuticals, Part 1: Overview of Protein and Peptide Degradation Pathways by Patel, J., et al., Available at: http://www.bioprocessintl.com/manufacturing/formulation/stability-considerations-for-biopharmaceuticals-part-1-332821/	ZOMIG00126506	ZOMIG00126527	authentication; hearsay; relevance; improper expert opinion; foundation
PX-172		Website: Brand Name Triptan, Available at: https://www.bcbsms.com	ZOMIG00126548	ZOMIG00126551	authentication; hearsay; relevance; improper expert opinion; foundation
PX-173		Website: Chemical Formula for Citric Acid, Available at: http://www.chemicalformula.org/citric-acid	ZOMIG00126552	ZOMIG00126553	authentication; hearsay; relevance; improper expert opinion; foundation
PX-174		Website: DDAVP Injection, Available at: www.webmd.com	ZOMIG00126574	ZOMIG00126578	authentication; hearsay; relevance; improper expert opinion; foundation
PX-175		Website: DDAVP Injection: Uses, Side Effects, Interactions, Pictures, Warning & Dosing, Available at: http://www.webmd.com/drugs/2/drug-6466/ddvap-injection/details	ZOMIG00126579	ZOMIG00126581	authentication; hearsay; relevance; improper expert opinion; foundation

PX	Date	Description	Beg Bates No.	End Bates No.	Objections
PX-176		Website: DrugBank: Zolmitriptan, Available at: http://www.drugbank.ca/drugs/DB00315	ZOMIG00126596	ZOMIG00126606	authentication; hearsay; relevance; improper expert opinion; foundation
PX-177		Website: Labrasol®, Available at: http://www.gattefosse.com/en/applications/labrasol.html	ZOMIG00126629	ZOMIG00126632	authentication; hearsay; relevance; improper expert opinion; foundation
PX-178		Website: Imitrex Vial 6 mg/0.5 ml - 5 Vials 5x0.5ml, Availabe at: http://www.rxzone.us/product.cfm/rx/Imitrex-Vial-6-Mg05-Ml-5-vials-234328.html	ZOMIG00127253	ZOMIG00127254	authentication; hearsay; relevance; improper expert opinion; foundation
PX-179		Website: Lazanda (fentanyl) Nasal Spray, Available at: http://www.lazanda.com/	ZOMIG00127405	ZOMIG00127408	authentication; hearsay; relevance; improper expert opinion; foundation
PX-180		Website: Miacalcin Nasal: Uses, Side Effects, Interactions, Pictures, Warning & Dosing, Available at: http://www.webmd.com/drugs/2/drug-14128/miacalcin-nasal/details	ZOMIG00127463	ZOMIG00127465	authentication; hearsay; relevance; improper expert opinion; foundation
PX-181		Website: Miacalcin Nasal, Available at: www.webmd.com	ZOMIG00127458	ZOMIG00127462	authentication; hearsay; relevance; improper expert opinion; foundation
PX-182		Website: Prescription Medications for Migraines - Association of Migraine Disorders, Available at: http://www.migrainedisorders.org/%20treatments/%20prescription-medications-migraines/	ZOMIG00127466	ZOMIG00127474	authentication; hearsay; relevance; improper expert opinion; foundation
PX-183		Website: Patanase (olopatadine hydrochloride) Nasal Spray Safety Information, Available at: http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm169926.htm	ZOMIG00127495	ZOMIG00127497	authentication; hearsay; relevance; improper expert opinion; foundation
PX-184		Website: Morphine (C17H19N03) Compound Summary, Available at: https://pubchem.ncbi.nlm.nih.gov/compound/morphine	ZOMIG00127498	ZOMIG00127577	authentication; hearsay; relevance; improper expert opinion; foundation
PX-185		Website: Buffer Reference Center, Available at: http://www.sigmaaldrich.com/life-sceince/core-bioreagents/biological-buffers/learning-center/buffer-reference-center.html	ZOMIG00128837	ZOMIG00128842	authentication; hearsay; relevance; improper expert opinion; foundation
PX-186		Website: Peptide Stability and Potential Degradation Pathways, Available at: http://www.sigmaaldrich.com/life-science/custom-oligos/custom-peptides/learning-center/peptide-stability.html	ZOMIG00128843	ZOMIG00128844	authentication; hearsay; relevance; improper expert opinion; foundation
PX-187		Website: Ketorolac Spray - Nasal, Available at: https://www.blueshieldca.com	ZOMIG00128885	ZOMIG00128887	authentication; hearsay; relevance; improper expert opinion; foundation
PX-188		Website: Synarel Nasal: Uses, Side Effects, Interactions, Pictures, Warnings & Dosing, Available at: http://www.webmd.com/drugs/2/drug-6479/synarel-nasal/details	ZOMIG00128894	ZOMIG00128896	authentication; hearsay; relevance; improper expert opinion
PX-189		Website: Synarel Nasal, Available at: www.webmd.com	ZOMIG00128889	ZOMIG00128893	authentication; hearsay; relevance; improper expert opinion; foundation
PX-190		Website: Vancenase Aq Nasal Spray 0.084% Information, Available at: https://www.drugs.com/drp/vancenase-aq-nasal-spray-0-084.html	ZOMIG00129115	ZOMIG00129124	authentication; hearsay; relevance; improper expert opinion; foundation
PX-191	8/19/1999	Article: Dahlof, C., Sumatriptan Nasal Spray in the Acute Treatment of Migraine: A Review of Clinical Studies, Cephalalgia, Vol. 19:769-778 (1999)			
PX-192	November 1998	Article: Diener, H.C., et al., A Practical Guide to the Management and Prevention of Migraine, Drugs, Vol. 56, Issue 5:811-824 (1998)	ZOMIG00126582	ZOMIG00126595	authentication; hearsay; relevance; improper expert opinion
PX-193	November 2015	Report: Highlights of Prescribing Information of Imitrex (sumatriptan succinate) Injection	ZOMIG00127227	ZOMIG00127252	authentication; hearsay; relevance; improper expert opinion; foundation
PX-194	12/16-12/18/2003	Article: Kagedal, M, et al., Zolmitriptan Demonstrates Good Pharmacokinetic Consistency Between and Within Individuals Following Intranasal Administration, British Journal of Clinical Pharmacology, Vol. 57, Issue 5:679-680 (2004)	ZOMIG00127370	ZOMIG00127396	authentication; hearsay; relevance; improper expert opinion; founation
PX-195	3/22/2008	Article: Lampl, C., et al., Difference in Triptan Effect in Pateitns with migraine and Early Allodynia, Cephalalgia, Vol 28:1031-1038 (2008)	ZOMIG00127397	ZOMIG00127404	authentication; hearsay; relevance; improper expert opinion
PX-196	2/27/2004	Article: Linde, M., et al., Sumatriptan (5-$HT_{1B/1D}$-agonist) Causes a Transient Allodynia, Cephalalgia, Vol. 24:1057-1066 (2004)	ZOMIG00127415	ZOMIG00127424	authentication; hearsay; relevance; improper expert opinion; founation

PX	Date	Description	Beg Bates No.	End Bates No.	Objections
PX-197	2008	Book: Rapoport, A.M., et al., Conquering Heading: An Illustrated Guide to Understanding the Treatment and Control of Headache, 6th Ed., BC Decker Inc.: Hamilton, Ontario (2008)	ZOMIG00127578	ZOMIG00127735	authentication; hearsay; relevance; improper expert opinion; founation
PX-198		Article: Rapoport, A.M., How to Choose a Preventive Medication for Migraine, American Headache Society	ZOMIG00127736	ZOMIG00127738	authentication; hearsay; relevance; improper expert opinion; founation
PX-199	1994	Article: Scott, A.K., Sumatriptan, Clinical Pharmacokinetics, Vol. 27, Issue 5:337-344 (1994)	ZOMIG00128814	ZOMIG00128821	relevance
PX-200	2001	Article: Yates, R., et al., P2-K29: Distribution and Pharmacokinetics of Zolmitriptan Following Administration by Nasal Spray, Cephalalgia, Vol. 21:405-432 (2001)	ZOMIG00129235	ZOMIG00129262	authentication; hearsay; relevance; improper expert opinion
PX-201	1/14/2004	Pleading: Patent Term Extension and New Patents, D.I. No. 95S-0117, January 14, 2004			hearsay; relevance
PX-202	2003	Article: Zingmark, P.H., et al. P5N36: True Nasopharyngeal Absorption of Zolmitriptan Following Administration of Zolmitriptan Nasal Spray, Cephalalgia, 23:581-762 (2003)	ZOMIG00129265	ZOMIG00129446	authentication; hearsay; relevance; improper expert opinion; founation
PX-203	10/18/2013	Report: 10/18/2013 1.3.5.2 Patent Certification	LAN_ZOLM00000327	LAN_ZOLM00000359	authentication; hearsay; relevance; foundation; incomplete (Rule 102)
PX-204		Spreadsheet: NPAs from 2003-2012	ZOMIG00024653	ZOMIG00024653	authentication; hearsay; relevance; foundation;incomplete; improper summary
PX-205		Spreadsheet: File Information for ZOMIG00125507	ZOMIG00125507	ZOMIG00125507	authentication; hearsay; relevance; foundation; incomplete; improper summary
PX-206		Website: Avanir Pharmaceuticals Announces FDA Approval of ONZETRA™ Xsail™ (AVP-825) for the Acute Treatment of Migraine in Adults, Available at: http://www.avanir.com/press/avanir-pharmaceuticals-announces-fda-approval-onzetra%E2%84%A2-xsail%E2%84%A2-avp-825-acute-treatment-migraine	ZOMIG00125676	ZOMIG00125680	authentication; hearsay; relevance; foundation; incomplete; improper expert opinion
PX-207		Website: Imitrex (Sumatriptan Succinate) - Description and Clinical Pharmacology, Available at: http://www.druglib.com/druginfo/imitrex/description_pharmacology/	ZOMIG00126607	ZOMIG00126611	authentication; hearsay; relevance; foundation; incomplete; improper expert opinion
PX-208	5/16/2013	Website: Press Release-Zydus Launches Migraine Drug Zolmitriptan in US, Available at: http://articles.economictimes.indiatimes.com/2013-05-16/news/39310516_1_zydus-cadila-173-andas-fy-2003-04	ZOMIG00126612	ZOMIG00126613	authentication; hearsay; relevance; foundation; incomplete; improper expert opinion
PX-209	May 2013	Website: First-Time Generic Drug Approvals - May 2013, Available at: www.fda.gov	ZOMIG00126614	ZOMIG00126614	authentication; hearsay; relevance; foundation; incomplete; improper expert opinion
PX-210		Website: Route of Administration, Available at: www.fda.gov	ZOMIG00126615	ZOMIG00126620	authentication; hearsay; relevance; foundation; incomplete; improper expert opinion
PX-211		Website: Orange Book: Approved Drug Products with Therapeutics Equivalence Evaluations, Available at: http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No-021450&Product_No=044&table1=OB_Rx	ZOMIG00125516	ZOMIG00125517	authentication; hearsay; relevance; foundation; incomplete; improper expert opinion
PX-212		Website: Impax Generics Division, Available at: http://www.impaxlabs.com/our_divisions/impax_generics	ZOMIG00127255	ZOMIG00127256	authentication; hearsay; relevance; foundation; incomplete; improper expert opinion
PX-213		Website: Pharmacokinetics in Children by C.M. Berlin Jr., Available at: http://www.merckmanuals.com/professional/pediatrics/principles-of-drug-treatment-in-children/pharmacokinetics-in-children	ZOMIG00127454	ZOMIG00127457	authentication; hearsay; relevance; foundation; incomplete; improper expert opinion
PX-214	1998	Article: Behl, C.R., et al., Effects of Physicochemical Properties and Other Factors on Systemic Nasal Drug Delivery (1998)			
PX-215		Report: Gaines, P., Significant Figures and Uncertainty	ZOMIG00130504	ZOMIG00130505	authentication; hearsay; relevance; incomplete; improper expert opinion

PX	Date	Description	Beg Bates No.	End Bates No.	Objections
PX-216	1997	Book: Olmsted III, J. and Williams, G.M., Chemistry: The Molecular Science, Wm. C. Brown: Iowa (1997)	ZOMIG00130506	ZOMIG00130545	authentication; hearsay; relevance; incomplete; improper expert opinion
PX-217	9/23/2015	Pleadings: Joint Claim Construction Brief, Impax Laboratories, Inc. v. Lannett Holdings, Inc., et al., Case No. 14-cv-984, D.I. No. 49, September 23, 2015			hearsay; relevance
PX-218	October 2013	Report: Highlights of Prescribing Information of Zolmitriptan Nasal Spray, by Lannett Holdings, Inc.	LAN ZOLM00000014	LAN ZOLM00000043	authentication; hearsay; relevance; incomplete;
PX-219		Report: Appendicies from the Expert Report of Alan Rapoport, M.D.			heasay; relevance
PX-220	2016	Article: Winner, P., et al., Efficacy and Tolerability of Zolmitriptan Nasal Spray for the Treatment of Acute Migraine in Adolescents: Results of a Randomized, Double-Blind, Multi-Center, Parallel-Group Study (TEENZ), Headache, 1-13 (2016)	ZOMIG00130548	ZOMIG00130560	authentication; hearsay; relevance; foundation; incomplete; improper expert opinion
PX-221	3/22/2016	Patent: U.S. Patent No. 9,289,432 B2, Issued to Gizurarson			relevance; hearsay; improper expert opinion
PX-222	9/23/2015	Pleadings: Declaration of Sveinbjorn Gizurarson, Ph.D., Impax Laboratories, Inc. v. Lannett Holdings, Inc., et al., Case No. 14-cv-984, D.I. No. 50-5, September 23, 2015			relevance; hearsay; improper expert opinion
PX-223	1993	Article: Gizurarson, S., The Relevance of Nasal Physiology to the Design of Drug Absorption Studies, Advanced Drug Delivery Reviews, Vol. 11:329-347 (1993)			relevance; hearsay; improper expert opinion
PX-224	2/15/2005	Patent: U.S. Patent No. 6,855,332 B2, Issued to Gizurarson, et al.			relevance; hearsay; improper expert opinion
PX-225		Website: U.S. FDA Drug Definitions, Available at: http://www.registrarcorp.com/fdaguidance/fdadefinitions/drugs.jsp			relevance; hearsay; improper expert opinion
PX-226		Website: Zolmitriptan C16H21N3O2, Available at: http://www.chemspider.com/Chemical-Structure.54844.html	ZOMIG00130499	ZOMIG00130501	authentication; hearsay; relevance; incomplete; improper expert opinion
PX-227		Website: Compound Details of C16H21N3O2, Available at: httsp://www.emolecules.com/cgi-blin/more?vid=2129142	ZOMIG00130502	ZOMIG00130503	authentication; hearsay; relevance; incomplete; improper expert opinion
PX-228	September 2013	Report: Highlights of Prescribing Information of Zomig (zolmitriptan) Nasal Spray	SUMMIT00000194	SUMMIT00000244	authentication; hearsay; relevance; foundation; incomplete; improper expert opinion
PX-229		Website: About the Journal of Education, Available at: http://pubs.acs.org/page/jceda8/about.html	ZOMIG00130494	ZOMIG00130495	authentication; hearsay; relevance; foundation; incomplete; improper expert opinion
PX-230		Website: Avogadro's Number, Available at: https://www.britannica.com/science/Avogardros-number	ZOMIG00130496	ZOMIG00130498	authentication; hearsay; relevance; incomplete; improper expert opinion
PX-231		Website: Definition of Ingredient, Available at: https://www.vocabulary.com/dictionary/ingredient	ZOMIG00130546	ZOMIG00130547	authentication; hearsay; relevance; incomplete; improper expert opinion
PX-232	8/28/2003	Patent: International Patent Application No. WO 03/070280 A2, Issued to Gizurarson, et al.			relevance; hearsay; improper expert opinion
PX-233		Website: Spray Bottle and Nebulizer Limitations, Available at: http://www.kruvetech.com/nasaldruglimitations.asp			relevance; hearsay; improper expert opinion
PX-234	2/8/1996	Correspondence: February 8, 1996 Letter Glaxo Wellcome PLC to Zeneca Limited re Memorandum of Understanding on 311C90	ZOMIG00001304	ZOMIG00001326	authentication; hearsay; relevance; foundation; incomplete; improper expert opinion
PX-235	3/15/1996	[redacted]	ZOMIG00001208	ZOMIG00001287	authentication; hearsay; relevance; foundation; incomplete
PX-236	9/20/1996	[redacted]	ZOMIG00000174	ZOMIG00000347	authentication; hearsay; relevance; foundaton; incomplete
PX-237	11/25/1999	Correspondence: November 25, 1999 Letter Zeneca Limited and AstraZeneca UK Limited to Glaxo Wellcome Inc., The Wellcome Foundation Limited, and Glaxo Wellcome PLC re Agreements	ZOMIG00000637	ZOMIG00000639	authentication; hearsay; relevance; foundation; incomplete; improper summary
PX-238	1/4/2000	[redacted]	ZOMIG00001346	ZOMIG00001350	authentication; hearsay; foundation

PX	Date	Description	Beg Bates No.	End Bates No.	Objections
PX-239	6/27/2000	[redacted]	ZOMIG00000353	ZOMIG00000358	authentication; hearsay; relevance; foundaion; incomplete
PX-240	1/22/2002	Correspondence: January 22, 2002 Letter AstraZeneca UK Limited to AstraZeneca AB re Patent Administration Services Arrangement	ZOMIG00001327	ZOMIG00001329	authentication; hearsay; relevance; foundation
PX-241	4/26/2002	[redacted]	ZOMIG00000640	ZOMIG00000643	authentication; hearsay; relevance; foundation
PX-242	2003	Article: Rapoport, A.M., et al., The Triptan Formulations: How to Match Patients and Products, CNS Drugs, Vol. 17, Issue 6:431-447 (2003)			relevance; hearsay; improper expert opinion
PX-243		Report: Yoshioka - Figures 52 and 71			relevance; hearsay; improper expert opinion; incomplete; foundation
PX-244		Image: Acid/Base Equilibrium			relevance; hearsay; improper expert opinion; incomplete; foundation
PX-245	1988	Book: Extract of Pages 254-268 of Aulton, M., Pharmaceutics: The Science of Dosage Form Design, 1st Ed., Churchill Livingstone: New York (1988)	ZOMIG00125621	ZOMIG00125641	authentication; hearsay; relevance; improper expert opinion; incomplete (Rule 102); foundation
PX-246		Website: Otrivin Nasal Spray, Available at: https://www.drugs.com/mmx/otrivin-nasal-spray.html			authentication; hearsay; relevance; improper expert opinion; incomplete (Rule 102); foundation
PX-247		Report: Sumatriptan Nasal Spray, USP (5 and 20 mg)	SUMMIT00006543	SUMMIT00006543	authentication; hearsay; relevance; foundation; incomplete; best evidence
PX-248	2002	Book: Extract of Pages from Yoshioka, S. and Stella, V., Stability of Drugs and Dosage Forms, Kluwer Academic Publishers (2002)	ZOMIG00120593	ZOMIG00120759	authentication; hearsay; relevance; improper expert opinion; foundation; incomplete
PX-249	September 2010	MIGRANAL NS Label - dihydroergotamine mesylate spray, Valeant Pharmaceuticals North America LLC	ZOMIG00121388	ZOMIG00121408	Not previously properly identified or produced in the litigation. Lannett reserves its rights to lodge any and all objections once the document is produced.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IMPAX LABORATORIES, INC., ASTRAZENECA AB, and ASTRAZENECA UK LIMITED,	)	
Plaintiffs,	)	C.A. No. 14-984-RGA
v.	)	(Consolidated)
LANNETT HOLDINGS, INC., and LANNETT COMPANY, INC.,	)	
Defendants.	)	

EXHIBIT 8

LANNETT'S PROPOSED TRIAL EXHIBITS

Pursuant to Local Rule 16.3(c)(6), Lannett provides below its list of trial exhibits that it intends to introduce into evidence during its case-in-chief. Lannett reserves the right to amend this list at any time, in accordance with the terms of the Pretrial Order or as otherwise permitted. Lannett reserves the right to introduce additional exhibits as rebuttal exhibits and/or for impeachment purposes as appropriate, including, where appropriate, introducing such rebuttal or impeachment exhibits into evidence. Further, Lannett reserves the right to use any of the Plaintiffs' exhibits and to supplement its exhibit list based upon the evidence admitted at trial.

Exh. No.	Document Description	Beg Bates Range	End Bates Range	Objections
DX-1	US Patent 6,326,401(Chauveu)	ZOMIG00122303	ZOMIG00122309	
DX-2	FR 2773489 (Chauveu)	ZOMIG00122358	ZOMIG00122395	F
DX-3	English Language Translation of FR 2772489 (Chauveu)	ZOMIG00122317	ZOMIG00122357	A/F, D
DX-4	US Patent 6,326,401(Chauveu) – including English language translation	ZOMIG00116736	ZOMIG00116742	C, A/F, D
DX-5	WO 99/64044 – Marquess	ZOMIG00117592	ZOMIG00117781	
DX-6	Remington's Pharmaceutical Sciences, Mack 30 Publishing Company, Easton, Pennsylvania, 19th Edition, 1995 (Remington 95)	ZOMIG00127739	ZOMIG00128791	I, D [Bates does not correspond to Remington 1995]
DX-7	Remington's Pharmaceutical Sciences, Mack 30 Publishing Company, Easton, Pennsylvania, 17th Edition, 1985 (Remington 85)	ZOMIG00129447	ZOMIG00130493	NP, NE, I, D [Bates does not correspond to Remington 1985]
DX-8	US 6,344,449 (Rudolf)	ZOMIG00116743	ZOMIG00116872	
DX-9	US 5,482,931 (Harris)	ZOMIG00116687	ZOMIG00116689	
DX-10	WO 97/25988 (Iyengar)	ZOMIG00123101	ZOMIG00123163	
DX-11	WO 98/47535 (Watts)	ZOMIG00123271	ZOMIG00123314	
DX-12	US Patent 5,4443,833 (Clark)	ZOMIG00116680	ZOMIG00116686	
DX-13	US Patent 4,504,470 (Uda)	ZOMIG00116611	ZOMIG00116619	
DX-14	McIlvaine, Journal of Biological Chemistry 49, 183(1921) (McIlvaine)	ZOMIG00116573	ZOMIG00116576	
DX-15	WO1998/002186 (Penkler I)	ZOMIG00123357	ZOMIG00123385	
DX-16	WO1998/002187 (Penkler II)	ZOMIG00116326	ZOMIG00116376	
DX-17	EP 0636623 (Robertson)	ZOMIG00128981	ZOMIG00129001	NE, R
DX-18	GB 2315673 (Sandquist)	ZOMIG00126633	ZOMIG00126657	NE, R
DX-19	WO 98/34595 (Keller)	ZOMIG00117512	ZOMIG00117558	R, NE
DX-20	Yeh, S-Y, Lach J.L. Stability of Morphine in Aqueous Solution III - Kinetics of Morphine Degradation in Aqueous Solution. Journal of Pharmaceutical Sciences, 1959 (Yeh)	ZOMIG00123497	ZOMIG00123504	I
DX-21	WO96/29074 (Johnson)	ZOMIG00123517	ZOMIG00123575	

Exh. No.	Document Description	Beg Bates Range	End Bates Range	Objections
DX-22	US 5,705,520 (Craig)	ZOMIG00129049	ZOMIG00129054	
DX-23	US 4,502,616 (Meierhoefer)	ZOMIG00116604	ZOMIG00116610	
DX-24	Japanese Laid Open Patent Publication No 3-115219 (Yano)	ZOMIG00116591	ZOMIG00116603	
DX-25	English language translation of Japanese Laid Open Patent Publication No 3-115219 (Yano)	ZOMIG00123661	ZOMIG00123678	A/F, F
DX-26	Japanese Laid Open Patent Publication No 11-255654 (Aikawa)	ZOMIG00123697	ZOMIG00123714	A/F, F
DX-27	English language translation of Japanese Laid Open Patent Publication No 11-255654 (Aikawa)	ZOMIG00116578	ZOMIG00116590	A/F, F
DX-28	US 4,782,047 (Benjamin)	ZOMIG00116620	ZOMIG00116625	
DX-29	US 5,397,771 (Bechgaard et al.)	ZOMIG00116644	ZOMIG00116679	
DX-30	EP 0417930 (Fujioka)	ZOMIG00116421	ZOMIG00116679	
DX-31	EP 0486854 (Bolasco)	ZOMIG00116465	ZOMIG00116468	
DX-32	EP 0489217 (Tosi)	ZOMIG00116469	ZOMIG00116475	
DX-33	WO 99/40900 (Alam).	ZOMIG00117559	ZOMIG00117591	
DX-34	US 5,037,845 – Oxford	ZOMIG00123925	ZOMIG00123939	
DX-35	US 6,576,224 (Osbakken)			NE
DX-36	US 5,484,776 (Racz)	ZOMIG00129002	ZOMIG00129009	
DX-37	US 5,374,659 (Gowan)			
DX-39	US 5,215,755 (Roche)			
DX-40	US 7,727,552 (Ukai)			
DX-41	US 6,045,778 (Jager)			
DX-42	US 4,226,848 (Nagai)			
DX-43	US 6,184,220 (Turck)	ZOMIG00129055	ZOMIG00129074	D [Bates does not correspond to Turck]
DX-44	Pharmaceutical Development Report - Zolmitriptan Nasal Spray, 5mg	LAN_ZOLM00000163	LAN_ZOLM00000245	NE
DX-45	Zolmitriptan Nasal Spray, 5 mg; 3.2.P.1 Description And Composition Of The Drug Product	LAN_ZOLM00000364	LAN_ZOLM00000364	NE
DX-46	Zolmitriptan Nasal Spray, 5 mg; 3.2.S.1.1	LAN_ZOLM00001563	LAN_ZOLM00001564	NE

Exh. No.	Document Description	Beg Bates Range	End Bates Range	Objections
	Nomenclature			
DX-47	Zolmitriptan Nasal Spray, 5 mg; 1.14.2.2 - Initial US Approval - 1997	LAN_ZOLM00005629	LAN_ZOLM00005653	NE
DX-48	Summit Biosciences Inc., - Part No. 9021 - Material Specification	LAN_ZOLM0006249	LAN_ZOLM0006253	R, NE
DX-49	Summit Biosciences Inc., - RA-005 - Risk Assessment - Enantiometric Purity Testing	LAN_ZOLM0006445	LAN_ZOLM0006455	R, NE
DX-50	Zolmitriptan Nasal Spray, 5 mg; 3.2.P.5.8.3 Stability Data	LAN_ZOLM0006776	LAN_ZOLM0006887	NE
DX-51	Zolmitriptan Nasal Spray, 5 mg; 3.2.s.4.5 Justification for Specification	LAN_ZOLM0006894	LAN_ZOLM0006895	NE
DX-52	Method Verification Report - Zolmitriptan Drug Substance (PLIVA API)	LAN_ZOLM0007154	LAN_ZOLM0007184	NE
DX-53	Method Validation Report - Zolmitriptan Drug Substance (Pliva API)	LAN_ZOLM00007228	LAN_ZOLM0007266	NE
DX-54	TRIAL 311CIL/014 - Erratum	ZOMIG00061420	ZOMIG00061787	NE, LF, R
DX-55	History and Limitations - Zomig Product Review 4/9-10/2002	ZOMIG00007152	ZOMIG00007189	R, NE, LF, I
DX-56	AstraZeneca Zolmitriptan Nasal Spray USP Monograph Proposal Important Notes	ZOMIG00115427	ZOMIG00115540	LF
DX-57	Performance Test Record - Auto Clave Trays Loading Log	ZOMIG00058526	ZOMIG00058564	I, NE, LF
DX-58	Validation Of Analytical Procedures Of The Drug Product	ZOMIG00058147	ZOMIG00058215	NE, LF
DX-59	AstraZeneca NDA Annual Report	ZOMIG00008617	ZOMIG00008632	NE, LF
DX-60	2-14-00 Email from J. Christenson to J. Sawyer re Zomig and LTA	ZOMIG00024330	ZOMIG00024330	R, NE, LF
DX-61	Summary of Notes of Meeting with Glaxo Wellcome 8-14-1996	ZOMIG00125508	ZOMIG00125513	R, NE, LF, P, H
DX-62	Approval Package for US FDA NDA Application No. 20626 (Imitrex/Sumatriptan), August 26, 1997 (Approval Date) (Sumatriptan Approval Package – 1			R, LF, NE, H, NP, NE

Exh. No.	Document Description	Beg Bates Range	End Bates Range	Objections
DX-63	Approval Package for US FDA NDA Application No. 20-626/S-001 (Imitrex/Sumatriptan), June 01, 2000 (containing Original Labeling) (Sumatriptan Approval Package – 2)	ZOMIG00115676	ZOMIG00115721	R, LF, NE, H, NE
DX-64	Stability of Drugs and Dosage Forms, Yoshioka and Stella, 2002 (Yoshioka)	ZOMIG00120593	ZOMIG00120866	
DX-65	Chemical Stability of Pharmaceuticals – A Handbook for Pharmacists, Second Edition, Conners, Amidon and Stella, 1986 (Conners)			
DX-66	Drug Stability: Principles and Practices Second Edition, Cartensen, 1995			
DX-67	Stability of cisapride in a liquid dosage form at two temperatures, Nahata et. al., The Annals of Pharmacotherapy • 1995 February, Volume 29 • 125 (Nahata)			
DX-68	The Stability of an Enalapril Maleate Oral Solution Prepared From Tablets, Boulton, Woods, Fawcett and Tucker, Australian J. of Hospital Pharmacy Vol. 24, No. 2, 1994 (Boulton)			
DX-69	Effect of pH and Storage Conditions on the Stability of a Novel Chloroquine Phosphate Syrup Formulation, Odusote and Nasipuri, Pharm. Ind. 50, Nr. 3 (1998) (Odusote)			
DX-70	Stability of Hydralazine Hydrochloride in Parenteral Solutions, Halasi and Nairn, Can. J. Hosp. Pharm 1990; 5: 237 0 241 (Halasi)			NE, R
DX-71	Stability of hydralazine hydrochloride in Aqueous vehicles, Gupta et al., Journal of Clinical and Hospital Pharmacy (1986) 1 1,2 15-223 (Gupta)			
DX-72	Sumatriptan nasal spray in the acute treatment of migrane: a review of clinical studies, Dahlof, Cephalalgia, 1999; 19:769-78 (Dahlof)	ZOMIG00115777	ZOMIG00115781	NE, R, D [Bates does not correspond to Dahlof]
DX-73	Dimerization of sumatriptan as an efficient way to design a potent, centrally and orally active 5-HT1b agonist, Perez et al., Bioorganic &			

Exh. No.	Document Description	Beg Bates Range	End Bates Range	Objections
	Medicinal Chemistry Letters 8 (1998) 675-680 (Perez)			
DX-74	Multiple-Attack Efficacy and Tolerability of Sumatriptan Nasal Spray in the Treatment of Migraine, Diamond et. al., Arch Fam Med. 1998; 7:234-240 (Diamond)			
DX-75	The Ph Of The Throat, Nose And Ear, Fabricant, N D, Journal: eye, ear, nose & throat monthly, Volume: 43 Pages: 60 Published: 1964-Mar) (Fabricant)			
DX-76	Po and Senozan, The Henderson-Hasselbach Equation: Its History and Limitations, Journal of Chemical Education, JChemEd.chem.wisc.edu, Vol. 78, No. 11, Nov. 2001			
DX-77	Barrow et al., The Absorption, Pharmacodynamics, Metabolism And Excretion Of 13C-Sumatriptan Following Intranasal Administration To The Beagle Dog, Biopharmaceutics & Drug Disposition, Vol. 18:5, 443-458 (1997)	ZOMIG00116441	ZOMIG00116456	
DX-78	Behl, Effects of physicochemical properties and other factors on systemic nasal drug delivery, Advanced Drug Delivery Reviews 29 (1998) 89-116			
DX-79	Chien, Transnasal Systemic Medications, Fundamentals, Developmental Concepts and Biomedical Assessments, 1985 (Chien I)			
DX-80	Chein, Nasal Systemic Drug Delivery, 1989 (Chien II)			
DX-97	WO96/00071 (Majeti)			R
DX-98	WO99/39732 (Avramis)			R
DX-99	Guidance for Industry: Q1B Photostability Testing of New Drug Substances and Products, November 1996, ICH (Guidance)			

Exh. No.	Document Description	Beg Bates Range	End Bates Range	Objections
DX-100	Experimental and computational approaches to estimate solubility and permeability in drug discovery and development settings," Lipinski et. al., Advanced Drug Delivery Reviews 23 (1997) 3-25) (Lipinski)			
DX-101	Sumatriptan Nasal Spray	SUMMIT00006543	SUMMIT00006543	LF, R, NE
DX-102	ZOMIG Nasal Spray – Development of a unit dose nasal spray	SUMMIT00044504	SUMMIT00044522	LF, R, NE, A/F, P, H
DX-103	2.3P Quality Overall Summary Drug Product	SUMMIT00000368	SUMMIT00000392	NE
DX-104	Letter dated September 8, 2015 to Office of Generic Drugs	SUMMIT00004463	SUMMIT00004523	NE
DX-105	Tfelt-Hansen, Efficacy and adverse events of subcutaneous, oral, and intranasal Sumatriptan used for migraine treatment: a systematic review based on number needed to treat, Department of Neurology, Bispebjerg Hospital, Copenhagen, Denmark 1998	ZOMIG00116211	ZOMIG00116217	
DX-106	Glen, Computer Aided Design and Synthesis of 5-Substituted Tryptamines and Their Pharmacology at the 5-HT1D Receptor; Discovery of Compounds with Potential Anti-Migraine Properties, J.Med.Chem 1995 (Glen)	ZOMIG00115829	ZOMIG00115843	
DX-107	Curriculum Vitae of Sveinbjorn Gizurarson,Ph.D.			H, LF
DX-108	Curriculum Vitae of Jinnian Gao, Ph.D.			H, LF

OBJECTION KEY

WP: Work Product (FRE 502)
R: Relevance (FRE 401, 402)
P: Prejudicial/Confusing/Collateral (FRE 403)
NE: Not cited in expert reports or cited but not discussed

NP: Not produced in fact discovery or otherwise provided
LF: Lacks Foundation
H: Hearsay
MD: Multiple Documents
A/F: Authentication/Foundation (FRE 901/602)
AC: Attorney-Client Privilege (FRE 502)
BE: Best Evidence Rule (FRE 1001-1004)
C: Cumulative (FRE 403)
D: Misleading or Incomplete Description
F: Foreign Language Document that does not include certified translation
I: Incomplete (FRE 106)

PLAINTIFFS' GENERAL OBJECTIONS AND RESERVATIONS

- Plaintiffs' object to the failure to identify Bates ranges for documents produced in this case, or deposition/witness identifications.
- Plaintiffs objections to Lannett's exhibits do not imply that the listed exhibits would not be properly introduced by Plaintiffs (as opposed to Lannett).
- Plaintiffs object to Lannett's reservation to use exhibits listed on Plaintiffs' exhibit list.
- Plaintiffs object to listed exhibits which do not correspond with the identified Bates range.
- Plaintiffs object to Lannett's use of unidentified exhibits.
- All objections for an item marked as a duplicate apply to all duplicates (or duplicate portions) of that item.
- Plaintiffs reserve the right to amend its objections to Lannett's exhibit list including after the exchange of actual exhibits.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IMPAX LABORATORIES, INC.,
ASTRAZENECA AB, and
ASTRAZENECA UK LIMITED,

Plaintiffs,

v.

LANNETT HOLDINGS, INC. and
LANNETT COMPANY, INC.,

Defendants.

C.A. No. 14-984-RGA
(Consolidated)

PRE-TRIAL ORDER EXHIBIT 9:
PLAINTIFFS' WITNESS LIST

Pursuant to Local Rule 16.3(c)(7), Plaintiffs Impax Laboratories, Inc., AstraZeneca AB, and AstraZeneca UK Limited (collectively "Plaintiffs") identify the following witnesses who they may call live or by deposition at trial.

I. EXPERT WITNESSES

Below are the expert witnesses Plaintiffs will call as live witnesses at trial.

a. Professor Hugh D. Smyth, Ph.D.

b. Dr. Alan Rapoport, M.D.

c. Professor Alexander M. Klibanov, Ph.D.

d. Any witness called live or by deposition by Defendants

II. FACT WITNESSES

Below are the fact witnesses that Plaintiffs may call either live or by deposition at trial.

a. Gregg Clark

b. Jinnian Gao

c. Kristie Stephens (by deposition designation)

d. Arthur Bedrosian (by deposition designation)

e. Any witness called live or by deposition by Defendants

The above list is not a commitment that Plaintiffs will call any particular witness at trial, or a representation that any of the witnesses listed are available or will appear for trial. If any witness listed as a person who Plaintiffs intend to call to testify in person is unavailable, Plaintiffs reserve the right to offer deposition testimony from such witness in lieu of live examination. Plaintiffs further reserve the right to introduce testimony through deposition or live examination for any witness that Defendants Lannett Holdings, Inc. and Lannett Company, Inc. (collectively, "Lannett") identify; for any expert witness that prepared an expert report on behalf

of Lannett in this action; or as necessary to establish authenticity or admissibility of any trial exhibit if the authenticity or admissibility of the exhibit is challenged by Lannett.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IMPAX LABORATORIES, INC., ASTRAZENECA AB, and ASTRAZENECA UK LIMITED,	)	
Plaintiffs,	)	C.A. No. 14-984-RGA (Consolidated)
v.	)	
LANNETT HOLDINGS, INC., and LANNETT COMPANY, INC.,	)	
Defendants.	)	

EXHIBIT 10 – LANNETT'S LIST OF WITNESSES FOR ITS CASE-IN-CHIEF

Pursuant to Local Rule 16.3(c)(7), and consistent with their initial disclosures pursuant to Fed. R. Civ. P. 26(a)(1) (including the timely served supplement thereto), Defendants Lannett Holdings, Inc. and Lannett Company, Inc. (collectively "Lannett") hereby serve their list of witnesses to be called in their case-in-chief. As presently advised, each of the witnesses identified on the attached list will provide live testimony, but Lannett reserves the right to present testimony for each of these witnesses by designation, reading and/or presentation of deposition testimony at trial. Lannett's list is based upon and limited to those witnesses identified individually or by specific category in its initial disclosures. In the event the Court permits the calling of witnesses not so identified in a party's initial disclosures, Lannett reserves the right to expand its witness list accordingly. In addition, Lannett reserves the right to call any of the listed witness, or any other witness, in rebuttal.

I. EXPERT WITNESSES

Witness
1. Dr. Sveinbjorn Gizuararson c/o Fox Rothschild LLP Joseph F. Posillico, Esq. 2000 Market Street Philadelphia, PA 19103 (215) 299-2000
2. Jinnian Gao Summit Biosciences Inc. c/o Fox Rothschild LLP Joseph F. Posillico, Esq. 2000 Market Street Philadelphia, PA 19103 (215) 299-2000

II. FACT WITNESSES

Witness
1. Arthur Bedrosian President and CEO Lannett c/o Fox Rothschild LLP Joseph F. Posillico, Esq. 2000 Market Street Philadelphia, PA 19103 (215) 299-2000

Witness
2. Suresh Potti R&D Project Manager Lannett c/o Fox Rothschild LLP Joseph F. Posillico, Esq. 2000 Market Street Philadelphia, PA 19103 (215) 299-2000
3. Jinnian Gao Summit Biosciences Inc. c/o Fox Rothschild LLP Joseph F. Posillico, Esq. 2000 Market Street Philadelphia, PA 19103 (215) 299-2000
4. Greg Plucinski Summit Biosciences Inc. c/o Fox Rothschild LLP Joseph F. Posillico, Esq. 2000 Market Street Philadelphia, PA 19103 (215) 299-2000
5. Patrick Kelly, Esq. Attorney Riverside Law 300 Four Falls Corporate Center, Suite 710 300 Conshohocken State Road West Conshohocken, PA 19428 Phone: 215-268-3888 Fax: 215-268-3871
6. Amy Allen Director Business Planning and Operations for Respiratory AstraZeneca LP

EXHIBIT 11 - PLAINTIFFS' DEPOSITION DESIGNATIONS

I. DEPOSITION OF ARTHUR BEDROSIAN (01/08/2016)

Plaintiffs' Designations	Defendants' Objections	Defendants' Counter-Designations[1]	Plantiffs' Objections to Defendants' Counter Designations
6:13-15			
10:25-11:17			
12:12-13:11			
14:9-16:7			
17:1-18:20	Relevance		
22:22-24	Outside the scope[2]		
23:6-10	Relevance; Outside the scope		
24:4-6	Relevance; Outside the scope		
24:9	Relevance; Outside the scope		
26:6-12			
34:5-35:2		35:5-15	Relevance
40:9-19	Relevance; outside the scope		
40:25-42:9			
42:18-45:5	Relevance		
45:11-16	Relevance		
46:22-47:1	Relevance	47:2-25; 48:1-6 *	Answer is non-responsive, Relevance, Calls for speculation
50:15-51:5	Relevance	51:6-25; 52:1-7 *	Calls for speculation, Lack of personal knowledge, Answer is non-responsive, Relevance
54:4-17	Relevance		
57:22-23	Relevance; outside the scope	57:2-21 *	Lack of personal knowledge, Relevance
58:1	Relevance; outside	57:2-21 *	Lack of personal

[1] Defendants' counter-designations for each witness are contingent upon the witness not being called to testify live at trial.

[2] Outside the scope of the deposition topic(s) for which the witness was designated pursuant to Fed. R. Civ. P. 30(b)(6)

Plaintiffs' Designations	Defendants' Objections	Defendants' Counter-Designations[1]	Plantiffs' Objections to Defendants' Counter Designations
	the scope		knowledge, Relevance
58:3-10	Relevance		
63:15-66:9	Relevance; Hearsay		
67:4-68:5	Relevance	68:6-11 *	Lack of personal knowledge, Relevance
90:14-91:2	Relevance		
119:2-3	Relevance; Foundation		
119:8-18	Relevance; Foundation		
127:7-128:9	Relevance		

II. DEPOSITION OF KRISTIE STEPHENS (01/29/2016)

Plaintiffs' Designations	Defendants' Objections	Defendants' Counter-Designations	Plantiffs' Objections to Defendants' Counter Designations
7:3-7			
8:21-9:10			
10:7-21			
12:16-19			
12:21-13:16			
14:8-18			
16:10-22			
18:2-8			
19:2-16			
24:14-15			
24:25-25:9			
25:19-26:11	Foundation		
26:14-24			
28:23-25	Outside the scope	27:21-25; 28:1-12 *	Improper designation, Lack of personal knowledge, Relevance, Answer is non-responsive
30:2-7	Relevance; Outside the scope	29:17-20 *	Relevance
33:2-4			
34:4-16			
35:13-23			
37:17-24			
38:6-18	Relevance		
47:7-16	Outside the scope		
48:4-9	Relevance	48:10-19 *	Relevance, Lack of personal knowledge, answer is non-responsive
51:23-52:6	Relevance		
52:13-22	Relevance; foundation		
52:25-54:25	Relevance; foundation		
55:4-8	Relevance; Outside the scope		
55:13-15	Relevance; Outside the scope		
55:17-56:24	Relevance; Outside	57:12-20; 58:6-10 *	Improper designation,

Plaintiffs' Designations	Defendants' Objections	Defendants' Counter-Designations	Plaintiffs' Objections to Defendants' Counter Designations
	the scope		Answer is non-responsive, Relevance
57:7-11	Relevance; Outside the scope	57:12-20; 58:6-10 *	Improper designation, Answer is non-responsive, Relevance
60:2-7	Relevance	62:5-9; 62:11-12 *	Answer is non-responsive, Relevance
67:16-68:6			
68:12	Outside the scope		
68:14	Outside the scope		
68:19	Outside the scope		
68:21-69:7	Outside the scope		
69:11-70:8	Relevance; Outside the scope; Hearsay		
70:20-24			
71:3-21	Outside the scope (71:18-21)		
71:25-72:20	Outside the scope		
73:1-74:9	Outside the scope		
74:18-23			
75:7-76:13	Outside the scope		
76:17-18	Outside the scope		
76:20-77:10	Outside the scope		
77:16-78:24		78:25; 79:1-5	Answer is non-responsive, Relevance
79:14-19			
80:6-8			
81:3-82:18			
83:11-85:1			
85:2-87:11			
95:9-14	Relevance; Outside the scope		
95:21-22	Relevance; Outside the scope		
96:23-97:11	Relevance; Outside the scope		
122:17-22			
156:13-19	Relevance; Outside the scope		
160:3-8	Outside the scope	160:9 *	
163:10-13	Relevance		
163:16-18	Relevance		

Plaintiffs' Designations	Defendants' Objections	Defendants' Counter-Designations	Plantiffs' Objections to Defendants' Counter Designations
165:5-15			

* - contingent upon the corresponding designation being found admissible

EXHIBIT 12

DEPOSITION TESTIMONY THAT DEFENDANTS MAY OFFER INTO EVIDENCE

Defendants currently plan to offer testimony only by live witnesses, and therefore at present have not designated any deposition testimony (other than their counter-designations indicated in Exh. 11). Defendants reserve their right to offer evidence by deposition designations in the event any live witness is unavailable, or in response to any additional deposition designations or trial testimony that may be offered by Plaintiffs and is not identified in this Pre-Trial Order.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IMPAX LABORATORIES, INC., ASTRAZENECA AB, and ASTRAZENECA UK LIMITED, Plaintiffs, v. LANNETT HOLDINGS, INC. and LANNETT COMPANY, INC., Defendants.	C.A. No. 14-984-RGA (Consolidated)

PRE-TRIAL ORDER EXHIBIT 13:
PLAINTIFFS' STATEMENT OF INTENDED PROOFS

Pursuant to Local Rule 16.3(c)(8), Plaintiffs Impax Laboratories, Inc., AstraZeneca AB, and AstraZeneca UK Limited (collectively "Plaintiffs") submit the following brief statement of the primary matters that Plaintiffs intend to prove at trial. Plaintiffs reserve the right to provide additional proof to rebut any proof offered by Defendants Lannett Holdings, Inc. and Lannett Company, Inc. (collectively, "Lannett") before or during trial, in response to rulings by the Court, or for any other good cause. Plaintiffs also reserve the right to supplement or amend this statement to fairly respond to any new issues that Lannett may raise. By including an issue herein, Plaintiffs do not assume the burden of proof, persuasion or production with respect to that issue. Plaintiffs incorporate by reference their expert reports and expert deposition testimony in support of any proof to be presented by expert testimony.

I. ISSUES ON WHICH PLAINTIFFS BEAR THE BURDEN OF PROOF, PRODUCTION OR PERSUASION

A. Infringement

1. Plaintiffs will prove, by a preponderance of the evidence, that by submitting ANDA No. 206-350 to the FDA and seeking approval to manufacture and sell its proposed product, Lannett has infringed claims 1–16 of U.S. Patent No. 6,750,237 (the "'237 patent") and claims 1–16 of U.S. Patent No. 7,220,767 (the "'767 patent"), either literally or under the doctrine of equivalents. Plaintiffs reserve the right to limit the number of asserted claims.

B. Secondary Considerations of Nonobviousness

2. Plaintiffs will also prove that secondary considerations of nonobviousness demonstrate that the claimed inventions are not obvious. Specifically, Plaintiffs will demonstrate that long-felt but unresolved need in the field met by the claimed inventions, Lannett's copying of Plaintiffs' products embodying the claimed inventions, acclaim in the industry, failure of others, skepticism in the industry, teaching away in the prior art, unexpected beneficial results,

and commercial success show that the claims of the '237 and '767 patents are non-obvious. Moreover, Plaintiffs will establish that the evidence of secondary considerations is commensurate with the scope of the claims and has a nexus to the claimed inventions.

II. ISSUES ON WHICH LANNETT BEARS THE BURDEN OF PROOF, PRODUCTION OR PERSUASION

3. Plaintiffs will, to the extent necessary, introduce evidence to rebut each of Lannett's affirmative defenses, including the defense of patent invalidity.

A. Alleged Anticipation and Obviousness of the Patents-in-Suit

i. The '237 Patent

4. Plaintiffs will show that Lannett is unable to, and has not, proven by clear and convincing evidence, that any asserted claim of the '237 patent is invalid for failure to comply with the requirements of 35 U.S.C. § 102. Further, Plaintiffs will show that Lannett cannot, and did not, prove by clear and convincing evidence that the asserted claims of the '237 patent are inherently or expressly anticipated by one or more pieces of prior art.

5. Plaintiffs will show that Lannett is unable to prove, and has not proven, by clear and convincing evidence, that any asserted claim of the '237 patent is invalid for failure to comply with the requirements of 35 U.S.C. § 103. In this regard, Plaintiffs will show that Lannett cannot, and did not, prove by clear and convincing evidence that any of the asserted claims of the '237 patent are invalid as obvious over the prior art, either alone or in combination with other art.

6. Plaintiffs will show that a person of ordinary skill in the art would not have been motivated to combine the prior art references asserted by Lannett in coming to the invention of the '237 patent. Plaintiffs will further show that a person of ordinary skill in the art would not

have had a reasonable expectation of success in making the claimed invention using any of the prior art references relied on by Lannett, either alone or in combination.

ii. The '767 Patent

7. Plaintiffs will show that Lannett is unable to, and has not, proven by clear and convincing evidence, that any asserted claim of the '767 patent is invalid for failure to comply with the requirements of 35 U.S.C. § 102. Further, Plaintiffs will show that Lannett cannot, and did not, prove by clear and convincing evidence that the asserted claims of the '767 patent are inherently anticipated by one or more pieces of prior art.

8. Plaintiffs will show that Lannett is unable to prove, and has not proven, by clear and convincing evidence, that any asserted claim of the '767 patent is invalid for failure to comply with the requirements of 35 U.S.C. § 103. In this regard, Plaintiffs will show that Lannett cannot, and did not, prove by clear and convincing evidence that any of the asserted claims of the '767 patent are invalid as obvious over the prior art.

9. Plaintiffs will show that a person of ordinary skill in the art would not have been motivated to combine the prior art references asserted by Lannett, in coming to the invention of the '767 patent. Plaintiffs will further show that a person of ordinary skill in the art would not have had a reasonable expectation of success in making the claimed invention of the '767 patent using any of the prior art references relied on by Lannett, either alone or in combination.

III. DAMAGES AND OTHER REMEDIES

10. Plaintiffs will demonstrate that Lannett's infringement of the asserted claims warrants a grant of permanent injunctive relief, and therefore requests that the Court grant such relief as appropriate, against any infringement of the Patents-in-Suit by Lannett, precluding it

from manufacturing, using, selling and/or offering to sell Lannett's proposed ANDA product in the United States, and/or importing it into the United States.

11. Further, Plaintiffs will demonstrate that Lannett's infringement of the asserted claims warrants a finding that the effective date of any approval of Lannett's ANDA No. 206-350 be not earlier than the expiration of the '237 or '767 patents, whichever is later, as extended by Plaintiffs' pediatric exclusivity, and respectfully requests that the Court issue such an order.

12. Plaintiffs reserve the right to seek attorneys' fees, costs and expenses pursuant to 35 U.S.C. § 285, and to seek damages in the event that Lannett manufactures, uses, sells, offers to sell, or imports its proposed ANDA product prior to the expiration of the of the '237 or '767 patent, whichever is later.

13. Plaintiffs further request a grant of such other and further relief as this Court may deem just and proper.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IMPAX LABORATORIES, INC., ASTRAZENECA AB, and ASTRAZENECA UK LIMITED, Plaintiffs, v. LANNETT HOLDINGS, INC., and LANNETT COMPANY, INC., Defendants.	C.A. No. 14-984-RGA (Consolidated)

EXHIBIT 14

LANNETT'S STATEMENT OF INTENDED PROOFS

Lannett submits the following brief statement of what it intends to prove at trial. In addition to the items identified below, Lannett may prove the matters identified in its interrogatory answers and in the expert reports, and depositions of its expert witnesses, and may also provide testimony concerning background information necessary to understanding the foregoing. Lannett also intends to offer proof on the issues of fact and issues of law identified in this Pre-Trial Order. Lannett also intends to offer proof to rebut the items on which Plaintiffs offer proof, and Lannett reserves the right to amend and supplement this statement in response to Plaintiffs' pretrial and trial positions.

I. INVALIDITY OF THE '237 AND '767 PATENTS

A. Novelty Pursuant to 35 U.S.C. § 102

Lannett will prove by clear and convincing evidence that the asserted claims of the '237 and '767 patents are invalid as anticipated by the prior art under 35 U.S.C. § 102 because each limitation of every claim is found expressly or inherently in a single prior art reference.

B. Obviousness Pursuant to 35 U.S.C. § 103

Lannett will prove by clear and convincing evidence that the asserted claims of the '237 and '767 patents would have been obvious to a person of ordinary skill in the art as of the effective priority date of those claims, in light of the scope and content of the prior art, the differences between each of these claims and the prior art, the level of ordinary skill in the art at the time, objective indicia of obviousness, and any proper objective indicia of non-obviousness submitted by Plaintiffs, and are therefore invalid.

II. REBUTTAL OF PLAINTIFFS' EVIDENCE

To the extent necessary, Lannett also intends to introduce evidence to rebut each of Plaintiffs' intended proofs, including without limitation alleged infringement of the asserted claims of the '237 and '767 patents and alleged secondary indicia of non-obviousness.

A. Non-Infringement of the Patents-in-Suit

Lannett will rebut Plaintiffs' evidence that Lannett's generic zolmitripan product that is the subject of ANDA No. 206350 ("Lannett's generic product") infringes each of the asserted claims of the '237 patent and '767 patent literally and under the doctrine of equivalents.

B. Objective Indicia of Non-Obviousness

Lannett intends to introduce evidence to rebut Plaintiffs' evidence of alleged secondary indicia of non-obviousness, including long-felt but unmet needs, failure of others, unexpected

results, industry acclaim, teaching away and skepticism by others, copying by others, commercial success, licensing, and any other indicia of non-obviousness presented by Plaintiffs.

Exhibit 15

PLAINTIFFS' *IN LIMINE* REQUESTS

PLAINTIFFS' *IN LIMINE* REQUEST #1 — TO PRECLUDE ARGUMENTS INCONSISTENT WITH THE COURT'S CLAIM CONSTRUCTION OPINION

In its Memorandum Opinion and Order regarding the term "zolmitriptan," this Court stated that "there is no dispute that the ordinary and customary meaning of 'zolmitriptan' ***includes*** ionically bonded forms of zolmitriptan." D.I. 60 at 8 (emphasis added). For its new non-infringement defense, Lannett argues the exact opposite—that "zolmitriptan" ***excludes*** ionically bonded forms of zolmitriptan. Impax moves to exclude that argument, which directly contradicts this Court's opinion and the parties' earlier agreement.

During claim construction briefing, Lannett admitted that the term "zolmitriptan" ***includes*** ionically bonded forms of zolmitriptan, such as salt forms including zolmitriptan citrate. It stated, for example, that the patent "equated the citrate salt of zolmitriptan with zolmitriptan," and that "*every* exemplary embodiment disclosed in the specification of the '237 and '767 patents includes the citrate salt of zolmitriptan." D.I. 49 at 17–18 (emphasis in original). Impax agreed, noting the parties' only dispute was whether the "term 'zolmitriptan' includes a covalently bonded 'form.'" D.I. 49 at 20.

At the Markman hearing, the Court recognized this limited dispute, as well as the parties' agreement that "zolmitriptan" ***includes*** ionically bonded forms (such as the citrate salt):

> THE COURT: And is your objection to their construction, the "ionic and covalently bonded forms," or is it, essentially, just to the "covalently bonded forms."
>
> [PLAINTIFFS' COUNSEL]: It's, essentially, just to the "covalently bonded forms," yes, your Honor.
>
> * * *
>
> THE COURT: Okay. So we're agreed that the citrate salt of zolmitriptan is an ionically bonded … [form of zolmitriptan]
>
> [LANNETT COUNSEL]: Yes, your Honor.

D.I. 59 at 23–24, 27. The Court's Memorandum Opinion framed the parties' areas of agreement

and disagreement in the same way:

> The parties agree that the term "zolmitriptan" encompasses a compound having the chemical name and basic chemical structure depicted above. (D.I. 49 at 18, 20). ***Further, there is no dispute that the ordinary and customary meaning of "zolmitriptan" includes ionically bonded forms of zolmitriptan.*** (*Id.* at 21; Tr. at 27–28). The parties disagree regarding whether "zolmitriptan" also includes covalently bonded forms of that structure that preserve the activity of the structure. (D.I. 49 at 20, 24).

D.I. 60 at 8 (emphasis added). The Court then addressed and analyzed the parties' dispute, finding that the disputed term did not include "covalently bonded" forms:

> I conclude that one of ordinary skill in the art would therefore not understand "zolmitriptan" to include covalently bonded forms of the chemical structure disclosed in the specifications as zolmitriptan.

Id. at 9. To reflect that holding, the parties submitted a proposed order on December 7, 2015 (D.I. Nos. 61–62) that contained the agreed chemical name and structure for zolmitriptan,[1] and the Court entered this as "So Ordered" on December 8, 2015 (D.I. 64). The Order is, at best for Lannett, silent on the question of whether the ionic salt form is covered, but the Court's Opinion makes clear what the answer is if the issue had been disputed.

After that agreed order adopted by the Court, Lannett asserted a new non-infringement argument premised on a hyper-literal (and incorrect) reading of the order. Contrary to its own prior statements, the parties' agreement, and the Court's recognition of the parties' agreement, Lannett now argues that the Court's claim construction "zolmitriptan" ***excludes*** ionically bonded forms of zolmitriptan, such as the citrate salt, and includes only what is known as the "free base"

[1] As noted by the Court in its Memorandum Opinion, the chemical name of zolmitriptan provided in the specification of the Patents-in-Suit contained an obvious typographical error. D.I. 60 at 9, fn. 1. The adopted construction merely corrects this obvious error. Moreover, as explained during the *Markman* process, zolmitriptan stays as zolmitriptan even when ionized because the resulting bond is transient, unlike a covalent bond. D.I. 49 at 21–22.

form of the drug. For example, Lannett's expert explains his (mis-)understanding as follows:

[redacted]

Ex. 1, Gizurarson Reb. Rep. at ¶ 41; *id.* at ¶ 50 (contending [redacted] (emphasis added)).

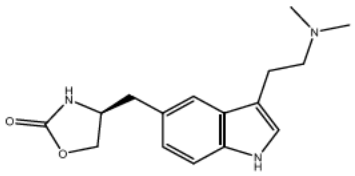
But the Court's formal order merely resolved the ***actual*** dispute between the parties: whether the term "zolmitriptan" includes "covalently bonded" forms of zolmitriptan. The Court's formal order did ***not*** address the parties' agreement that the term ***includes*** ionically bonded forms such as the citrate salt. The Court's Memorandum Opinion in fact directly refutes Lannett's mis-interpretation by noting that "the ordinary and customary meaning of 'zolmitriptan' ***includes*** ionically bonded forms of zolmitriptan" (D.I. 60 at 8 (emphasis added))—that is, ***not*** just limited to the free-base form. Indeed, Lannett's expert acknowledges that [redacted]. Ex. 2, Gizurarson Dep. Tr. at 110:18–111:2; *see also* D.I. 50-5 at Ex. Y (pp. 8–9) [redacted] Nothing in the record suggests that the Court intended such a nonsensical result, particularly considering that a "claim interpretation that excludes a preferred embodiment from the scope of the claim is rarely, if ever, correct." *Accent Packaging, Inc. v. Leggett & Platt, Inc.*, 707 F.3d 1318, 1326 (Fed. Cir. 2013).

For the foregoing reasons, and to avoid the parties and the Court expending significant time during the three-day trial fighting over what should be a settled issue, Plaintiffs respectfully request that its motion *in limine* be granted.

LANNETT'S OPPOSITION TO PLAINTIFFS' *IN LIMINE* REQUEST #1

Contrary to Plaintiffs' assertion, the Court's construction of "zolmitriptan" excludes ionically bonded forms. As Lannett explained in its *Daubert* Motion to exclude Dr. Smyth (the "Smyth *Daubert* Brief", D.I. 107), it is ***Plaintiffs*** that are misconstruing the Court's clear construction. In short, Plaintiffs successfully narrowed the meaning of "zolmitriptan" to avoid Lannett's prior art but now seek to improperly broaden the Court's construction because their narrow construction, induced by a concern about the prior art, precluded a finding of infringement. Lannett's generic contains no free-base zolmitriptan and cannot infringe the Patents-in-Suit under the Court's construction, which was adopted at Plaintiffs' request.

The Court construed the term "zolmitriptan," at Plaintiffs' request, as follows:

> Compound having the chemical name (S)-4-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-2-oxazolidinone and chemical structure:
>
> 

See Claim Construction Order (D.I. 64) at 1. This construction limits zolmitripan to the chemical **name** and **chemical structure** of free-base zolmitriptan. The construction does not include the **name** of any ionically-bonded form of zolmitriptan, which Plaintiffs acknowledged would have a different name than free-base zolmitriptan. *See* Transcript of *Markman* Hearing, D.I. 59, at 25:8-14, 18-24. While Plaintiffs now attempt to characterize such a reading as "hyper-literal" and "nonsensical," this was the exact construction they themselves proposed during the *Markman* phase. Indeed, it was Plaintiffs' counsel who drafted the proposed Claim Construction Order that was submitted to and executed by the Court. *Compare* Exhibit G (12/3/15 email and attachment) *with* Exhibit H (D.I. 64). Notably, [redacted] D.I. 107, at 6. Further, Plaintiffs' counsel unequivocally argued during the *Markman* hearing as follows:

> Finally, the ionic bond at issue, the claims require "zolmitriptan." They do not recite citrate salt of "zolmitriptan." The specification defines "zolmitriptan" as having a defined chemical name, which leads to a specific molecular weight and specific structure. The discussion of salts does not change the definition of "zolmitriptan." Specifically, it is not part of the molecule….

D.I. 59, at 42:18-24; s*ee also id*. at 25:8-24, where Plaintiffs' counsel admits that "[t]he ionically bonded form [of zolmitriptan] would have a different name [than zolmitriptan free base]."

Plaintiffs are now backpedaling from their own proposed construction to support their infringement theory by improper cherry-picking of the Court's discussion of Lannett's claim construction arguments. During claim construction, Plaintiffs argued that only the free-base form of zolmitriptan was covered by the claim term, while Lannett argued that all three forms — the "free base" form as well as covalently and ionically bonded derivatives—were covered by the term. In the Memorandum Opinion, the Court noted the parties' differing positions:

> The parties agree that the term "zolmitriptan" encompasses a compound having the chemical name and basic chemical structure depicted above. (D.I. 49 at 18, 20). Further, there is no dispute that the ordinary and customary meaning of "zolmitriptan" includes ionically bonded forms of zolmitriptan. (*Id.* at 21; Tr. at 27-28). The parties disagree regarding whether "zolmitriptan" also includes covalently bonded forms of that structure that preserve the pharmaceutical activity of the structure. (D.I. 49 at 20, 24).

D.I. 60, at 8. The Court further noted, however, that Lannett had argued that a construction including ionic but excluding covalently bonded forms would be "arbitrary." *Id.* Hence, faced with a choice to accept either Plaintiffs' or Lannett's proposed construction, the Court expressly chose to "adopt Plaintiffs' proposed construction" (D.I. 60 at 9)—a construction that was indisputably limited to the free-base form. D.I. 64 at 1.[2] Allowing Plaintiffs to broaden the scope of the term "zolmitriptan" on the eve of trial, after having successfully obtained their

[2] Indeed, if the Court wanted to revise Plaintiffs' proposed construction of "zolmitriptan" for clarity rather than simply adopting it verbatim, it would have done so, as it did with respect to the term "buffer." *See* D.I. 60 at 13 ("I adopt Defendants' functional definition….The Court's construction is expressed differently than Defendants' proposed construction for clarity.").

desired construction in December of last year, and after Lannett has relied upon this construction in preparing for trial, would be highly prejudicial to Lannett. Plaintiffs' attempt to alter the Court's claim construction is now barred by judicial estoppel. *See Stairmaster Sports/Medical Products, Inc. v. Groupe Procycle, Inc.*, 25 F. Supp. 2d 270, 278-80 (D. Del. 1998) (precluding plaintiff, under the doctrine of judicial estoppel, from rearguing construction of claim term during summary judgment in a manner inconsistent with position taken during *Markman* phase).

Plaintiffs' misguided position is rooted in the Court's dicta that "there is no dispute that the ordinary and customary meaning of 'zolmitriptan' includes ionically bonded forms of zolmitriptan." D.I. 60, at 8. Critically, however, the Court did not adopt the "ordinary and customary meaning" of the term "zolmitriptan" that includes both ionically and covalently bonded forms. Rather, the Court chose to adopt Plaintiffs' proposed construction—a construction that, as Plaintiffs argued in the *Markman* briefing, is based on the express definition of "zolmitriptan" found in the specifications of the Patents-in-Suit. *See* D.I. 49 at 15, citing *Jack Guttman, Inc. v. Kopykake Enterprises, Inc.*, 302 F.3d 1352, 1360 (Fed. Cir. 2002) (stating that the specification "acts as a dictionary when it expressly defines terms used in the claims"). The parties did not agree on the "ordinary and customary meaning" of "zolmitriptan," and the Court instead adopted the narrower construction advocated by Plaintiffs.

Finally, Plaintiffs' argument that "Lannett's new argument would exclude each example in the patent" should be rejected. Lannett advanced that very argument during the *Markman* phase and did not prevail. Plaintiffs should not be allowed to reverse course and now advocate for a position unsuccessfully argued by Defendants in order to avoid the consequences of their successful efforts to limit the claims for purpose of attempting to avoid prior art.

For the reasons stated above, Plaintiffs' *In Limine* Request No. 1 should be denied.

PLAINTIFFS' REPLY IN SUPPORT OF THEIR *IN LIMINE* REQUEST #1

Lannett fails in its attempt to reconcile its new "interpretation" of the Court's claim construction of "zolmitriptan" with what the Court actually did, or with common sense. Contrary to Lannett's arguments, the Court ***did not*** reject the ordinary and customary meaning of "zolmitriptan" in favor of a different meaning, and ***did not*** construe the term to exclude every single example and embodiment referenced in the patents. There is no suggestion anywhere that the Court adopted such an extraordinary construction, one which the case law says is "rarely, if ever, correct." *Accent Packaging, Inc. v. Leggett & Platt, Inc.*, 707 F.3d 1318, 1326 (Fed. Cir. 2013). Indeed, the Court expressly recited the parties' agreement that "there is no dispute that the ordinary and customary meaning of 'zolmitriptan' includes ionically bonded forms of zolmitriptan." D.I. 60 at 8. After walking through its analysis, the Court "conclude[d] that one of ordinary skill in the art would therefore not understand 'zolmitriptan' to include covalently bonded forms…." and never said it was adopting a construction that was ***inconsistent*** with the parties' agreement on ionically bonded forms. *Id.* at 9.

The parties were expected to, and did, propose an order consistent with the Court's Memorandum Opinion. While the Court's construction could have been (and can still be) further clarified to expressly reflect the parties' agreement on ionically bonded forms, in no way did the Court's construction exclude these forms. Following Lannett's logic, it would have this Court believe that the parties proposed an order that was inconsistent with their prior agreement on ionically bonded forms, inconsistent with the Court's recognition of this agreement, and which excluded all embodiments from the claims, without telling the Court this was happening. This defies common sense and conflicts with the actual record. Plaintiffs respectfully request the Court grant Plaintiffs' MIL #1 to avoid a sideshow on this issue at trial.

PLAINTIFFS' *IN LIMINE* REQUEST #2 — TO PRECLUDE DEFENDANTS FROM RELYING ON ITS CATCH-ALL OBVIOUSNESS ARGUMENT

Plaintiffs move to preclude Lannett's expert Dr. Sveinbjörn Gizurarson from discussing or otherwise raising his so-called "Obviousness Ground 10," a catch-all obviousness argument that seeks to preserve thousands of potential obviousness combinations based on nearly two dozen references. Even worse, the primary reference upon which any of these thousands of combinations might be based is undefined in its own right, simply referring generally to "Sumatriptan Nasal Spray" without any details as to what documentary or other evidence provides the basis for this alleged prior art.

Dr. Gizurarson has failed to sufficiently detail the underlying facts, evidence and basis for this catch-all Obviousness Ground No. 10. Dr. Gizurarson purports to detail this ground at ¶¶ 168 and 218 of his May 30, 2016 expert report (Ex. 3) where he states that every claim of both Patents-in-Suit are obvious [redacted] Although almost *two dozen* references (spanning several thousands of pages of disclosure) are cited, Dr. Gizurarson provides no explanation of how the various references or the practically unlimited number of combinations render each of the claims obvious. Indeed, [redacted] Dr. Gizurarson, however, does not stop there; he adds that [redacted]

[redacted] Ex. 3, Gizurarson Op. Rep. at ¶¶ 168, 218. In other words, Dr. Gizurarson's "Obviousness Ground 10" is any and every combination of the almost fifty alleged prior art references disclosed in his report, as well as "the skill level of a POSITA." *See id.* at pp. 5–8.

Dr. Gizurarson has failed to satisfy the requirements of Federal Rule of Civil Procedure 26(a)(2)(B), which requires "a *complete* statement of all opinions the witness will express *and* the basis and reasons for them." Moreover, this lack of specificity would cause Plaintiffs undue prejudice because they cannot prepare to address Dr. Gizurarson's "catch-all" opinion that the claims are obvious in view of every single possible combination of art cited in his report, particularly when the relied on disclosures of each reference are not even identified or discussed.

[redacted]

[3] Although he lists in his materials considered at p. 8 of his Opening Report, [redacted] of Combination 10 is intended to be this product or another formulation.

[redacted] Plaintiffs cannot even begin to address this obviousness ground without this information.[4] Moreover, Plaintiffs' expert, [redacted] Ex. 4, Klibanov Reply Rep. at ¶ 351. Despite submitting a reply report purporting to address Dr. Klibanov's opinions, Dr. Gizurarson failed to address the elephant in the room, namely Dr. Gizurarson's lack of specificity regarding this combination of references.

Because of the lack of specificity of Dr. Gizurarson's disclosed opinions, including a failure to provide pin-cites for the limitless references or a particular description of "Sumatriptan Nasal Spray" and evidence of what this prior art actually is, Dr. Gizurarson has failed to meet the requirements of Federal Rule of Civil Procedure 26(a)(2)(B). This will also prejudice Plaintiffs because Dr. Gizurarson has failed to identify which combination of references (let alone which portions of those references) will be relied on nor the basis for his conclusion that these combinations all render each claim obvious. Accordingly, the Court should preclude Dr. Gizurarson from relying on "Sumatriptan Nasal Spray" or any "catch-all" combination of references in his Obviousness Ground 10.

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[4] Although Dr. Gizurarson [redacted] he fails to describe what portion or portions of [redacted] formulation. Ex. 3, Gizurarson Op. Rep. at ¶¶ 168, 218. Craig is an alleged prior-art U.S. patent describing a number of sumatriptan formulations containing different constituent compounds; indeed, when discussing a different combination of references, Dr. Gizurarson notes [redacted] but Dr. Gizurarson fails to point to any particular formulation as the basis of his opinion. *Id.* at ¶ 160.

LANNETT'S OPPOSITION TO PLAINTIFFS' *IN LIMINE* REQUEST NO. 2

The Court should deny Plaintiffs' *In Limine* Request No. 2. Contrary to Plaintiffs' statements, Dr. Gizurarson's Obviousness Ground 10 is not "a catch-all obviousness argument," nor does it provide "thousands of potential obviousness combinations." Plaintiffs' criticisms of Dr. Gizurarson's opinions stem from a myopic view of his expert report. Plaintiffs focus only on a handful of pages of the report while ignoring the rest. When Dr. Gizurarson's opinions are properly considered in the context of his entire report, it is clear that his Obviousness Ground 10 is properly supported.

Dr. Gizurarson clearly lays out the basis for his Obviousness Ground 10. Contrary to Plaintiffs' statements, the primary reference, "Sumatriptan Nasal Spray" is clearly defined and supported by record documentary evidence. Dr. Gizurarson states as part of his Ground 10:

[redacted]

Gizurarson Report (Exh. 3 to Plaintiffs' MIL #2) ¶¶ 168, 218 (emphasis added). Plaintiffs ignore the clear reference to an earlier section of Dr. Gizurarson's report, in which he discusses [redacted]

Gizurarson Report ¶ 62. The citation here is clearly to [redacted]

5 [redacted]

[redacted]

The number of combinations in Dr. Gizurarson's Obviousness Ground 10 are not "practically unlimited" or "limitless" as Plaintiffs contend. Plaintiffs again mischaracterize Dr. Gizurarson's report ignoring his statements regarding the references relied upon and how they are grouped in his Ground 10. Dr. Gizurarson expressly provides a limited set of references that he combines [redacted]

[redacted]

[redacted] Clearly, the number and type of combinations in Dr. Gizurarson's Obviousness Ground 10 are well defined and not "limitless" as Plaintiffs contend. Moreover, as discussed below, elsewhere in his report, Dr. Gizurarson discusses each of these groups of prior art providing specific citations to each reference.

As they did with the primary Sumatriptan Nasal Spray reference, Plaintiffs ignore relevant sections of Dr. Gizurarson's report when they complain that he "provides no explanation" of how the references when combined with the primary reference render the claims obvious. Dr. Gizurarson provides a detailed discussion of the prior art and the knowledge of the ordinarily skilled artisan that he combines with the marketed sumatriptan nasal spray in his Obviousness Ground 10. For example, regarding category (i) above, Dr. Gizurarson provides a detailed discussion [redacted] *See* Gizurarson Report at ¶¶ 56-61, 86, 116-134, 161, 211. Likewise, Dr. Gizurarson provides a detailed discussion of the prior art in above categories (ii) to (iv). *See, e.g., id.*, at ¶¶ 103-111 (ii); ¶¶ 95-99, (iii); and ¶¶ 68-73 (iv). Plaintiffs' improperly ignore this disclosure in Dr. Gizurarson's Report.

Dr. Gizurarson provided a complete statement of his Obviousness Ground 10 and the basis and reason for his opinions and therefore satisfies the requirements of Rule 26(a)(2)(B). Accordingly, Plaintiffs' *In Limine* Request No. 2 should be denied.

PLAINTIFFS' REPLY IN SUPPORT OF THEIR *IN LIMINE* REQUEST #2

Lannett fails to cogently explain why it should be permitted to rely on its ***tenth*** "catch-all" obviousness argument seeking to preserve thousands of combinations of ill-defined prior art. Lannett's arguments about how it might disclose some of these references in the context of ***other*** combinations only support Plaintiffs' position; as such, Lannett should be precluded.

Plaintiffs invite the Court to review Dr. Gizurarson's report and attempt to decipher the sole paragraph (per patent) for Combination #10. Ex. 3, Gizurarson Rep. at ¶¶ 168, 218. Lannett does not dispute it lists dozens of references, incorporates dozens more, and identifies just one pin-cite among ***thousands*** of document pages. Lannett points to no specific citation of what "Sumatriptan Nasal Spray" is, and [redacted] never produced to Plaintiffs or cited by a Bates number—and [redacted] *Id.* at pp. 6–7. His vague reference to "Sumatriptan Nasal Spray" "[a]s described above" ***sixty pages*** later provides no clue as to what he relies on. There is no dispute he never discussed the approval packages, established them as prior art, cited them, nor identified any particular disclosure therein. There is also no dispute he stated there were ***multiple*** prior art sumatriptan formulations.

Lannett's argument as to the number of combinations also belies belief—their opposition argument alone lists almost twenty references, and ignores [redacted] *Id.* at ¶¶ 168, 218. Dr. Klibanov called Dr. Gizurarson's attention to this issue, but Dr. Gizurarson ignored him in his reply report. Lannett's expert provided no decipherable, specific disclosure of the grounds for his catch-all argument, and Plaintiffs' request to exclude this ***tenth*** obviousness argument should be granted.

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[6] Lannett's opposition attaches only a ***non-prior art*** approval package.

PLAINTIFFS' *IN LIMINE* REQUEST #3 — TO PRECLUDE DEFENDANTS FROM CALLING CERTAIN IMPROPERLY DISCLOSED FACT WITNESSES AT TRIAL

Plaintiffs move to preclude Lannett from calling three fact witnesses at trial that were not properly disclosed, and thus not deposed, during fact discovery. Plaintiffs took the depositions of the persons and entities that were identified by Lannett as having knowledge regarding the issues relevant to the case, but did not take depositions of persons that were not disclosed, or were disclosed to have knowledge that is irrelevant to the remaining issues. The three fact witnesses that are the subject of this motion are:

- Greg Plucinski, Summit Biosciences Inc. Chief Operating Officer;
- Suresh Potti, Lannett R&D Project Manager; and
- Patrick Kelly, Esq.

Lannett provided nothing during fact discovery to suggest that these three witnesses possessed important or even relevant information for this case, and Plaintiffs would be severely prejudiced if they are permitted to testify. Plaintiffs thus respectfully request that Lannett be precluded from calling these witnesses at trial.

First, with respect to Mr. Plucinski, he was not identified by Lannett in initial disclosures or otherwise in response to any written discovery. Mr. Plucinski's company, Summit Biosciences, was involved in formulating and manufacturing the accused product for Lannett. As part of its response to Impax's request for leave to file a summary judgment motion on the issue of infringement, Lannett provided the Court a declaration from Summit's Associate Director of Pharmaceutical Development, Dr. Jinnian Gao, to support their non-infringement position. D.I. 72-7. Impax subsequently served a deposition subpoena on Summit and deposed Dr. Gao as Summit's corporate designee on various subjects, including the ingredients and formulation of the accused product. Given that Dr. Gao will be separately testifying at trial (and

provide relevant information from Summit) and that Mr. Plucinski was never identified as an individual with knowledge, Plaintiffs object to Lannett's inclusion of Mr. Plucinski on its witness list.

Second, Lannett's inclusion of Lannett employee Suresh Potti on its witness list is even more puzzling given Lannett's prior statements in this case. Lannett has recently informed Plaintiffs that it may call Mr. Potti to testify about the "ingredients" (*i.e.*, formulation) of the accused product. But Lannett previously told Impax and the Court that ***no one at Lannett*** possessed this knowledge, and that Plaintiffs would have to take this discovery from Summit (which Plaintiffs did via the deposition of Dr. Gao, noted above). Lannett specifically told the Court in a February 26 letter:

> Plaintiffs served a Rule 30(b)(6) notice on Lannett including topics directed to, *inter alia*, "the active pharmaceutical ingredient and chemical structure thereof" for the accused products. In December 2015 ***Lannett notified Plaintiffs that they did not have a corporate representative with sufficient knowledge to testify on the deposition topics relating to the formulation of the accused product***.[FN] Lannett informed Plaintiffs that information relating to this topic could be obtained from Lannett's supplier of the accused product as identified in Lannett's Abbreviated New Drug Application, Summit Biosciences, Inc.

D.I. 72 at 3–4 (emphasis added). Thus, while Mr. Potti had been identified in Lannett's disclosures at the outset of the case, Lannett expressly told Plaintiffs and the Court that it did not have a witness that could address "the formulation of the accused product." In light of this representation, Plaintiffs will be unfairly prejudiced if Lannett is now permitted to call Mr. Potti to supplement or contradict the testimony of the Summit witness (Dr. Gao) that Lannett actually identified during discovery on this subject. On the other hand, Lannett will not be prejudiced if it cannot call either Mr. Plucinski or Mr. Potti because it intends to call Dr. Gao, who it identified during discovery as a person "most knowledgeable" about formulation of the accused product

and Lannett's non-infringement allegations. Ex. 5, Lannett's Second Supp. Resp. to Plaintiffs' 2nd Set of Interrogatories at 2–7.

Finally, Lannett's indication that it may call attorney Patrick Kelly at trial might be the most puzzling of all. Mr. Kelly's name appears on no documents produced in the case. Mr. Kelly has not served any expert declaration or other disclosure. Lannett's supplemental disclosures, and Lannett's recent explanation of Mr. Kelly's potential relevance, refer to his knowledge of the "non-willfulness of any infringement." Yet Plaintiffs have not even pled willfulness in this case, and have no intention of presenting willfulness evidence at trial.[7] As a result, Lannett has no basis to call Mr. Kelly at trial and should be precluded from doing so.

Lannett's attempt to bolster their new non-infringement theory through these new witnesses—based on an interpretation of the claims which was injected into this case *after* the Court already decided the proper meaning of the term "zolmitriptan"—should not be countenanced. Not only does the underlying legal theory lack merit for the reasons detailed in Plaintiffs' Motion *In Limine* #1, but Lannett has failed to properly disclose these witnesses to the detriment of Plaintiffs. Accordingly, Plaintiffs request that the Court preclude Lannett from calling Greg Plucinski, Suresh Potti, and Patrick Kelly, Esq., or in the alternative, permit the deposition of these fact witnesses prior to trial.

[7] Lannett's supplemental disclosures also suggest that Mr. Kelly has knowledge regarding "the invalidity of the patents-in-suit," but Lannett did not identify that topic as one on which it intends to call Mr. Kelly, and in any event Impax does not believe Mr. Kelly could testify on this ultimate legal issue in the absence of serving an expert report in this case.

LANNETT'S OPPOSITION TO PLAINTIFFS' *IN LIMINE* REQUEST #3

The Court should deny Plaintiffs' motion to preclude the testimony of Suresh Potti, Patrick Kelly, and Greg Plucinski because Plaintiffs had notice that each of these witnesses may be called at trial to testify, and the subject matter of their respective testimony. Lannett's ability to present its case-in-chief should not be limited because of the Plaintiffs' failure to conduct adequate discovery by deposing these witnesses.

Notably absent from Plaintiffs' request to exclude the testimony of these witnesses is any legal authority in support of their position. This is because "courts within the Third Circuit have been reluctant to exclude otherwise admissible evidence in the absence of extreme neglect or bad faith on the part of the proponent of the testimony." *In re Joy Global, Inc.*, 423 B.R. 445, 450 (D. Del. 2010) (citations omitted). Plaintiffs fail to even attempt to argue that such circumstances exist here because they cannot.

Plaintiffs have been aware of Mr. Potti and Mr. Kelly since at least as early as December 5, 2014, when both were listed in Lannett's Rule 26(a)(1) disclosures. *See* Exhibit J (Lannett's Initial Disclosures). Both Mr. Potti and Mr. Kelly remained on Lannett's supplemental disclosures. *See* Exhibit K (Lannett's First Supplemental Initial Disclosures). Mr. Potti, in particular, was disclosed as a person with discoverable information regarding "components of the product accused of infringement." Ex. J at 2; *see also* Ex. K at 2.

Despite being on notice of Mr. Potti, Plaintiffs failed to depose him. Now, on the eve of trial, Plaintiffs attempt to excuse their failure by conflating relevant information regarding *formulation* of the accused product with information regarding the *components* of the accused products. While these topics may be related, they are by no means the same. In general, components refer to the "what" of the accused product, whereas the formulation refers to "how"

these components are combined. Indeed, as provided in Lannett's supplementation, Lannett has indicated that there is a distinction between information regarding components and formulation. *See* Ex. K at 3 (identifying "[o]ne or more technical witnesses from Summit Biosciences Inc." as having discoverable information regarding "[t]he ***formulation***, ***components***, characteristics and/or features of the product accused of infringement"). Therefore, contrary to Plaintiffs' assertion, Mr. Potti's area of knowledge is not duplicative of Dr. Jinnian Gao's testimony.

Like Mr. Potti, Mr. Kelly has been listed on Lannett's Initial Disclosures since the outset of this case. Specifically, Mr. Kelly was disclosed as a person with discoverable information regarding "[t]he invalidity of the patents-in-suit." Ex. J at 2; Ex. K at 2. Plaintiffs' argument that Mr. Kelly's testimony is not relevant because they do not intend on presenting willfulness at trial is a red herring because Plaintiffs continue to seek relief on the basis that this is an exceptional case under 35 U.S.C. § 285. Considering that the Plaintiffs sought such relief in their Complaint, their basis must necessarily be at least in part predicated on Lannett's pre-litigation activity. *See* Complaint (D.I. 1), at 10. Courts will consider advice of counsel when determining whether the pre-litigation activities of a party are such that would support a finding of an exceptional case. *See e.g., Ortho Pharmaceutical Corp. v. Smith*, 959 F.2d 936, 944-945 (Fed. Cir. 1992). As long as Plaintiffs maintain their request for relief under Section 285, Lannett reserves the right to call Mr. Kelly to testify regarding his legal advice to Lannett prior to the commencement of this litigation about the invalidity of the Patents-in-Suit—the exact subject of information that is identified in Lannett's Rule 26(a) disclosures.

Plaintiffs were on notice that Mr. Plucinski may be called as a technical witness at trial because Lannett's supplemental disclosures identified "[o]ne ***or more*** technical witnesses from Summit Biosciences Inc." having discoverable information regarding "[t]he formulation,

components, characteristics and/or features of the product accused of infringement." *See* Ex. K at 2 (emphasis added). During his deposition, [redacted] *See* Exhibit L (Transcript of Deposition of Jinnian Gao, Ph.D.), at 35:21 to 37:14. Therefore, from at least the time of Dr. Gao's deposition, Plaintiffs should have been aware that Mr. Plucinski was a specific individual who was employed by Summit and who possessed relevant information in the category that Lannett had identified in its supplemental initial disclosure.

In short, despite being aware of Mr. Potti and Mr. Kelly for over a year-and-a-half, and Mr. Plucinski as a category of witness since February and as a specific witness at least since the deposition of Dr. Gao, Plaintiffs did not even attempt to take their depositions. Plaintiffs should not now be allowed to leverage their own lack of diligence to exclude the relevant testimony of these witnesses. *See In re Joy Global, Inc.*, 423 B.R. at 450 (denying motion to exclude testimony of witnesses who were identified in Rule 26(a)(1) disclosure and supplementation reasoning that moving party "did not, though it could have, sought the depositions of [these witnesses] that were disclosed as having had information relevant to" the case).

Accordingly, for at least the reasons stated above, this Court should deny Plaintiffs' *In Limine* Request No. 3.

PLAINTIFFS' REPLY IN SUPPORT OF THEIR *IN LIMINE* REQUEST #3

Lannett's opposition to Plaintiffs' *in limine* request #3 confuses rather than clarifies how Plaintiffs were allegedly on fair notice of Messrs. Potti, Plucinski, and Kelly. Based on Lannett's statements during discovery, Plaintiffs reasonably chose to depose other individuals identified as having relevant knowledge. Lannett refuses to explain why it now needs these witnesses when it has others that have more relevant knowledge and have been deposed. Plaintiffs will be prejudiced if these three non-deposed witnesses are permitted to testify.

Suresh Potti*:** Lannett seeks to explain away its prior discovery position—that Lannett did not have ***any witness that could testify about the accused formulation—by arguing that apparently Mr. Potti has information about "components" of the formulation albeit not the "formulation" itself. Even if this is credited, it only means Lannett successfully misled Plaintiffs during discovery to not take Mr. Potti's deposition. Plaintiffs do not understand how Mr. Potti has non-duplicative knowledge about "components" when Summit's Dr. Gao was identified as "most knowledgeable" and deposed about this. Mr. Potti is not needed and should be excluded given Lannett's prior statements; alternatively, Plaintiffs should be allowed to depose Mr. Potti.

Greg Plucinski*:** Lannett acknowledges Mr. Plucinski was neither deposed nor even identified during the discovery period as a person with knowledge. Lannett argues that, since it stated "one or more" Summit persons might have knowledge, it can call whomever it wants from Summit. This is inconsistent with the discovery rules and basic norms of fair play. And Dr. Gao's mention of Mr. Plucinski during deposition—taken ***after the close of discovery because Lannett's counsel delayed—never put Plaintiffs on notice that Plucinski would be a trial witness.

Patrick Kelly: Lannett has stated they have no present intention of calling Mr. Kelly given that willfulness is not part of the case, so this issue is moot.

Exhibit 16

DEFENDANTS' *IN LIMINE* REQUESTS

LANNETT'S *IN LIMINE* REQUEST NO. 1

Lannett submits this motion *in limine* to preclude Plaintiffs from calling in their case in chief witnesses that Plaintiffs failed to disclose pursuant to Fed. R. Civ. P. 26(a)(1).

A. Background

As part of preparing the pretrial order, Plaintiffs have submitted a witness list that discloses for the first time four "fact" witnesses they intend to call in their case that they have never before identified as required under Fed. R. Civ. P. 26(a)(1): (i) Gregg Clark, an Impax employee and 30(b)(6) witness whom Plaintiffs have never identified as possessing relevant personal knowledge for their case; (ii) Jinnian Gao, a Summit employee and expert retained by Lannett; (iii) Kristie Stephens; (iv) and Arthur Bedrosian, both employees of Lannett.[1] None of these individuals, nor the subject matter of their "fact" testimony, has been identified by Plaintiffs in required disclosures pursuant to Fed. R. Civ. P. 26(a)(1) (Exh. A), which disclosures Plaintiffs never supplemented since they were initially served on December 5, 2014. As a result of Plaintiffs' eleventh hour identification of these claimed fact witnesses, Lannett now has no opportunity to prepare for this undefined and unanticipated fact testimony that Plaintiffs now intend to introduce in its case in chief. Indeed, none of these witnesses were deposed by Lannett as possible fact witnesses for the Plaintiffs. Accordingly, Lannett moves to preclude the Plaintiffs from calling in their case in chief any fact witnesses that were not properly identified in their required Rule 26 disclosures.

B. Exclusion of these new fact witnesses is required under the circumstances.

Preclusion of evidence and testimony is a sanction used against parties who have failed to

[1] Lannett's *in limine* request with respect to Ms. Stephens and Mr. Bedrosian applies only to the extent that Plaintiffs intend to call them as live witnesses—i.e., if Plaintiffs only intend to introduce their testimony by way of deposition designation (as they have so indicated on their Witness List), this *in limine* request will not apply to their testimony.

comply with their discovery obligations. *Stambler v. RSA Sec., Inc.*, 212 F.R.D. 470, 471-72 (D. Del. 2003) (precluding late-disclosed witnesses from testifying); *Konstantopoulos v. Westvaco Corp.*, 112 F.3d 710, 719 (3d Cir. 1997) (affirming exclusion of late-disclosed witness). Under the Federal Rules, a party is required to disclose potential witnesses "that the disclosing party may use to support its claims or defenses . . . ." Fed. R. Civ. P. 26(a)(1)(A). Further, the disclosing party is under a duty to supplement the disclosure if the party learns that in some material respect the information disclosed is incomplete or incorrect . . . ." Fed. R. Civ. P. 26(e). The purpose of this disclosure is to alert an opposing party of the need to take discovery of the named witness with respect to the identified subject matter. *Degelman Indus. Ltd. v. Pro-Tech Welding and Fabrication Inc.*, 2011 WL 6754059, at *2 (W.D.N.Y. June 3, 2011). Although Lannett had notice that the individuals listed in Plaintiffs' exhibit list are involved in this case, a party's mere knowledge of the existence of a witness is insufficient to alert the party that the opposing party might call the witness in support of its claims or defenses. *Id.*

Here, Lannett is unaware of what factual information Plaintiffs' proposed witnesses will be testifying to at trial. For instance, while Mr. Clark was produced as a 30(b)(6) witness on several categories (many of which he had little or no relevant personal knowledge), he was not deposed with respect to any potential trial testimony as he was not identified as an individual likely to have discoverable information under Rule 26(a)(1)(A)(i). Similarly, Lannett had no reason or opportunity to depose Mr. Gao, its own expert and third party, or either of the two Lannett employees. Thus, Lannett had no notice of the factual testimony that Plaintiffs intend to rely on and hence no opportunity to develop a record at deposition on these subjects. Plaintiffs provided no indication of these witnesses' expected testimony, giving Lannett no means of ascertaining the materiality of each individual's testimony. Plaintiffs failed to comply with Rule

26(e). The Scheduling Order required the parties to exchange initial disclosures by December 5, 2014, but Plaintiffs put Lannett on notice of these witnesses only last week.

Witnesses that are not disclosed pursuant to Rule 26(a) or (e) can be excluded at trial. A party that fails to disclose or supplement its disclosures "is not allowed to use that information or witness to supply evidence…at a trial, unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1). The Third Circuit considers five factors when deciding whether to preclude evidence under Rule 37: (1) the prejudice to or surprise of the party against whom the evidence is offered; (2) the ability of that injured party to cure the prejudice; (3) the likelihood of disruption of trial; (4) the bad faith or willfulness involved in not complying with the disclosure rules; and (5) the importance of the evidence to the proffering party. *See Konstantopoulos*, 112 F.3d at 719.

Plaintiffs' untimely disclosure of their fact witnesses prejudices and surprises Lannett, who now has no time to take discovery of the named witnesses in this late stage before trial. *See Stambler*, 212 F.R.D. at 471 (finding that plaintiff in patent case will "clearly be prejudiced" if witnesses disclosed after close of fact discovery are permitted to testify). Lannett also has no time to cure this prejudice as the deadline for fact discovery has passed and trial is in a matter of weeks. Plaintiffs' late disclosure will disrupt trial as Lannett has no time to prepare for the testimony of these witnesses. *See id.* at 472 (finding that "allowing these witnesses [disclosed late] to testify will disrupt the orderly and efficient resolution of this case."). Plaintiffs had 19 months to comply with the disclosure rules, but never disclosed that any of the individuals on their witness list are relevant to their claims or defenses. Also, Plaintiffs gave no reason why these witnesses were disclosed so late in the discovery period. Thus, Plaintiffs' failure to disclose is neither justifiable nor harmless.

PLAINTIFFS' RESPONSE TO DEFENDANTS' *IN LIMINE* REQUEST #1

The rhetoric in Lannett's *in limine* request #1, which seeks preclusion of all four fact witnesses identified on Plaintiffs' witness list, simply bears no connection to reality. Lannett's feigned surprise is undercut by the fact that ***each of these four witnesses was identified and deposed during discovery***. Two of the four (Arthur Bedrosian and Kristy Stephens) are Lannett's own employees, and are in fact the only two Lannett employees that were deposed in the case. A third (Jinnian Gao) is an employee of Summit, the formulator and manufacturer of the accused product, and was the individual that Lannett identified as being the most knowledgeable regarding the formulation of the accused product. Lannett even submitted a fact declaration from this Summit employee, and he has been deposed as both a fact and expert witness in the case. The final witness (Gregg Clark) is the only Impax employee that was deposed in this case, and his anticipated trial testimony will be well within the 30(b)(6) topics on which he was designated and deposed in May. There can be no credible claim of surprise that any of these witnesses might testify at trial, and Lannett's *in limine* request should be denied.

The case law cited by Lannett in support of its exclusion argument actually supports Plaintiffs. In each of the cases cited by Lannett, the "late-disclosed witnesses" were neither identified nor deposed during fact discovery. That is not the case here. Although difficult to make sense of Lannett's argument, Lannett's position is apparently that any witness not listed on Plaintiffs' initial disclosures should be precluded from testifying. But Lannett cites no precedent to support this particular argument, and Lannett's own cases refute it. As Lannett itself states in its motion, the purpose of the disclosure rules "is to alert the opposing party of the need to take discovery of the named witnesses with respect to the identified subject matter." Lannett Br. at 2. Lannett had this notice, and each of these witnesses has been deposed on the subjects of their

anticipated testimony.

The irony of Lannett's "surprise" and "prejudice" arguments is that for three of the witnesses, Lannett is in a better position to know what they will say than are Plaintiffs. Two of the witnesses, Arthur Bedrosian and Kristy Stephens, are Lannett's own employees. And despite Lannett's feigned ignorance in its motion, Plaintiffs have told Lannett that they do not want or need these witnesses live, and instead only intend to play brief portions of their depositions. There can be no surprise whatsoever as to what these witnesses will testify to. And if Lannett wants to call these witnesses—their own employees—live, that is their prerogative to do so.

With respect to Summit's Associate Director of Pharmaceutical Development, Dr. Jinnian Gao, Lannett similarly cannot credibly claim surprise that he is a potential trial witness or as to what he might say. Dr. Gao was identified by Lannett as the person "most knowledgeable" about formulation of the accused product and Lannett's non-infringement allegations. Ex. 5, Lannett's Second Supp. Resp. to Plaintiffs' 2nd Set of Interrogatories at 2–7. Lannett also filed with the Court a declaration from Dr. Gao dated February 26, 2016 providing details as to how the accused product is formulated. D.I. 72-7. Dr. Gao was deposed as a fact witness on June 1, 2016, and was prepared for this deposition, and defended at the deposition, by Lannett's counsel from Fox Rothschild. Subsequently, on July 12, 2016, Lannett served a rebuttal expert report authored by Dr. Gao. He was then deposed in his capacity as an expert witness on August 5, 2016, again represented by Lannett's counsel from Fox Rothschild. Lannett has had every opportunity to ask questions of Dr. Gao at his two depositions. And given that Lannett itself intends to call Dr. Gao as a witness at trial, they will have the opportunity to elicit his live testimony as well. Lannett's argument to exclude Dr. Gao as a witness simply makes no sense.

Lannett's exclusion arguments similarly make no sense for Impax Director of Marketing

Gregg Clark. Lannett deposed Mr. Clark in May on numerous 30(b)(6) topics issued to Plaintiff Impax, including "The marketing, distribution, licensing, and sales of any Commercial Embodiment of the Asserted Patents." Ex. 6, Lannett's 30(b)(6) Deposition Notice to Impax.[2] Plaintiffs intend to call Mr. Clark as a live witness at trial to testify as to the marketing, distribution, licensing and sales of Zomig® NS, the commercial embodiment of the patents-in-suit. Given that the scope of Mr. Clark's testimony will be well within the scope of the deposition that Lannett noticed and took in May, there can be no credible claim of surprise regarding his testimony. *Cf. Price v. Code Alarm, Inc*. 1992 WL 390895 (N.D. Ill. Dec. 16, 1992) (finding designation of witnesses in response to 30(b)(6) notice was sufficient to meet the requirements of Rule 26); *Moore v. Computer Associates Intern., Inc.*, 653 F.Supp.2d 955, 959 (D. Ariz. 2009) (agreeing with defendant's assertion in response to motion to exclude affidavit that because witness was "designated under Federal Rule of Civil Procedure 30(b)(6)," "Rule 26 disclosure was not required"); *see also, e.g., 3Com Corp. v. Realtek Semiconductor Corp.*, 2008 WL 783383 (N.D. Cal. Mar. 24, 2008) (finding unpersuasive identification in initial disclosures but finding persuasive fact that witness had been deposed).

Lannett's *in limine* arguments to exclude all of Plaintiffs' potential fact witnesses have no merit whatsoever. There has been no "late disclosure" of these witnesses—they were all deposed—and there is no credible claim of surprise or prejudice. Plaintiffs respectfully request that Lannett's *in limine* request #1 must be denied.

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[2] Although the Court may recall that there was a dispute and motion practice regarding certain topics in Lannett's 30(b)(6) notice, there was no objection with respect to the above-identified topic and several related topics, and Lannett's counsel had a full opportunity to ask questions on these topics (and thus they were not the subject of the motion).

LANNETT'S REPLY IN SUPPORT OF ITS *IN LIMINE* REQUEST NO. 1

Plaintiffs obscure the difference between deposing a Rule 30(b)(6) designee and identifying individuals who could be called as a fact witness at trial. Rule 26 requires a party to provide notice of discoverable information. Rule 30(b)(6) allows a party to depose a corporate employee, not in his individual capacity, but as the voice of the corporation, about narrowly-defined topics. Plaintiffs failed to notify Lannett that either its, Lannett's or Summit's 30(b)(6) designees had information that Plaintiffs might present in their case-in-chief at trial. Thus, allowing these witnesses to testify at trial would prejudice Lannett, as Lannett took the discovery and/or prepared its case in reliance on the fact that Plaintiffs never placed any of these persons on its initial disclosure list.

Plaintiffs' identification of Mr. Clark as their 30(b)(6) designee in response to Lannett's discovery request does not relieve Plaintiffs of their obligation to identify witnesses. Plaintiffs never identified Clark as a person who might be a witness, so Lannett deposed Clark on the basis that Plaintiffs would not be calling him to testify at trial. Had he been properly identified, Lannett would have conducted the deposition and prepared its case much differently. Arthur Bedrosian, Kristie Stephens and Jinnian Gao were identified as its 30(b)(6) designees, but defending these depositions in no way put Lannett on notice that Plaintiffs would call any of these persons in their case-in-chief. Reflective of Plaintiffs' failure to take its disclosure obligations seriously, even today Plaintiffs have still not identified what information they think these witnesses have that would be useful to Plaintiffs if they were called for live testimony at trial. Plaintiffs had over nineteen months to supplement their required disclosures and failed to do so. Only now, on the eve of trial, Plaintiffs attempt to dodge any consequences of their non-compliance and usher in back-door fact witnesses to the prejudice of Lannett.

LANNETT'S *IN LIMINE* REQUEST NO. 2

Lannett respectfully moves to preclude Plaintiffs from presenting evidence on secondary considerations of nonobviousness because they have failed to establish the most basic foundation for such evidence—that the claims of the Patents-in-Suit cover the commercial product held out by Plaintiffs as forming the basis for the alleged secondary considerations.

A. Background

Lannett has asserted that the claims of the patents-in-suit are invalid as obvious over certain prior art. In response, Plaintiffs have attempted to introduce evidence of secondary considerations of non-obviousness through expert testimony, without any factual basis that ties the purported secondary considerations to the elements claimed in the Patents-in-Suit. Plaintiffs attempt to substantiate all of their claimed secondary considerations, including commercial success; long-felt, but unmet need; failure of others; unexpected results; industry acclaim; skepticism and teaching away; copying; and licensing solely by reference to Plaintiffs' Zomig NS product offered commercially in the market. *See* Reply Report of Alan Rapoport, M.D. ("Rapoport Report," Exh. B) ¶¶ 38-132; Reply Report of Professor Alexander Klibanov ("Klibanov Report," Exh. 4 to Plaintiffs' MIL #2) ¶¶ 357-377. Fatal to their claims of secondary considerations, however, Plaintiffs have produced no chemical or other forensic analysis, data or admissible evidence from which it can be shown that Zomig NS is covered by any of the claims of the patents-in-suit. There is no such documentary evidence anywhere in the record, and none of Plaintiffs' three experts or two 30(b)(6) witnesses provide any factual testimony to establish that the asserted claims of the patents-in-suit cover Zomig NS. For instance, there is no evidence of record that Zomig NS in fact contains an effective amount of zolmitriptan free base as required by the asserted claims as construed by the Court.

B. Plaintiffs' Experts Do Not Provide Any Technical or Factual Basis for Any Asserted Claims to Cover Zomig NS

Neither Dr. Klibanov nor Dr. Rapoport supports his opinion by establishing or referring to any evidence tying the patent claims to the Zomig NS product. [redacted] Rapoport Report ¶¶ 32, 34), [redacted] (*id.*, ¶ 69, *see also* ¶¶ 77, 97, 107). Likewise, [redacted]

Apparently aware of the deficiency in the opinions that discuss secondary considerations, Dr. Smyth (Plaintiffs' infringement expert) also asserts [redacted] There is no legal basis for these assertions, however, as the Orange Book merely includes the patents that the product manufacturer, i.e., Plaintiffs, unilaterally identifies. Likewise, Lannett's Orange Book certification does not have any evidentiary bearing on whether the patent claims at issue cover Plaintiffs' product. *Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 10 F. Supp. 2d 446, 456 (D. N.J. 1998) (Orange Book listing creates no presumption that a patent is listed correctly; the FDA

lacks resources and expertise to review submitted patents); 21 U.S.C. § 355(b)(1).

C. Plaintiffs Should Be Precluded from Providing Testimony on Secondary Considerations

Federal Rule of Civil Procedure 26(a)(2)(B) requires that a witness retained or specially employed to provide expert testimony must provide a written report which contains "a complete statement of all opinions the witness will express and the basis and reasons for them." *Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp.*, 289 F. Supp. 2d 493, 500 (D. Del. 2003) (holding that testimony not disclosed in an expert's report would not be considered by the court). "As noted in the case law of this jurisdiction, the testimony of expert witnesses is limited to the information contained in their expert reports." *Id.*; *see also Moore N. Am., Inc. v. Poser Business Forms, Inc.*, 2001 WL 253117, at *7 (D. Del. Mar. 8, 2001) (precluding a party from asserting a defense where the party's expert report was silent on it); *Arthrocare Corp. v. Smith & Nephew, Inc.*, 2003 WL 1905636, at *1 (D. Del. April 14, 2003) (excluding certain expert testimony because "experts are limited by their reports").

The repeated incantation of [redacted]. Without such a showing, there can be no nexus between the claimed secondary considerations that the experts assert the Zomig NS product demonstrates, and the asserted patent claims of the Patents-in-Suit. *See, e.g., Wyers v. Master Lock Co.*, 616 F.3d 1231, 1245 (Fed. Cir. 2010); *Cot'n Wash, Inc. v. Henkel Corp.*, 56 F. Supp. 3d 626, 650 (D. Del. 2014). Accordingly, Lannett respectfully requests that the Court preclude Plaintiffs from: presenting at trial any testimony regarding secondary considerations of nonobviousness that rely on a nexus to the Zomig NS product; or from trying to introduce at this late date any evidence that the Zomig NS product meets the limitations of the asserted claims.

PLAINTIFFS' RESPONSE TO DEFENDANTS' *IN LIMINE* REQUEST #2

Lannett's second request, to preclude Plaintiffs from presenting any evidence on secondary considerations of nonobviousness, is yet another meritless attempt to obtain draconian relief regarding an important issue in this case. The Federal Circuit has explained that secondary considerations "must always when present be considered" in support of non-obviousness,[3] and Lannett offers no reason to create an exception in this case. Lannett's only argument for ignoring this evidence is that the commercial embodiment of the patents-in-suit—Zomig® Nasal Spray (Zomig® NS) marketed for treatment of migraine headaches by Impax—is somehow not an embodiment of the patent claims. But there is no serious dispute that Zomig® NS embodies the claims, except for Lannett's misinterpretation of the Court's claim construction of "zolmitriptan" to argue non-infringement of the accused product and non-practice by Zomig® NS (*see* Plaintiffs' MIL #1). At best, Lannett's arguments go to the weight and not admissibility of Plaintiffs' evidence on secondary considerations, and the motion must be denied.

There is substantial and undisputed evidence that Zomig® NS is an embodiment of what is described and claimed in the asserted patents. First, Plaintiffs' experts have unequivocally stated and provided such evidence. Second, Lannett's own witnesses have admitted that Zomig® is a commercial embodiment of the patents-in-suit, but for the same argument they make for non-infringement purposes regarding the Court's claim construction of the term "zolmitriptan." Lannett also ignores that their proposed product (for which Plaintiffs' expert Dr. Smyth provided a claim-by-claim analysis) is a ***copy*** of Zomig®—this is an ANDA case and the evidence of record establishes Lannett's product is quantitatively *and* qualitatively an effort to be ***the same as Zomig NS***.

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[3] *See In re Cyclobenzaprine*, 676 F.3d 1063, 1075–76, 1079 (Fed. Cir. 2012).

Drs. Rapoport and Klibanov have submitted detailed expert reports on various issues including secondary considerations of non-obviousness, and they have stated [redacted] *See, e.g.*, Ex. 7, Rapoport Rep. at ¶ 119; Ex. 4, Klibanov Reb. Rep. at ¶ 72. What Lannett also fails to mention is that [redacted] Ex. 8, Smyth Op. Report at ¶ 26. Moreover, Dr. Smyth details that Lannett's generic product [redacted] *Id.* at ¶ 28. And in his rebuttal report, he further points to a Summit document [redacted] Ex. 9, Smyth Rep. Report at ¶ 56; *see also id.* at ¶ 58 (discussing the [redacted][4] He also discusses how Dr. Gizurarson's claim construction would [redacted] *Id.* at ¶ 23. Throughout both of his expert reports, [redacted] As such, it is clear that Dr. Smyth's analysis—the analysis Lannett wrongly suggests is missing—is the same for both products.

If Lannett had any issue with how Dr. Smyth conducted his analysis, it had the opportunity to present rebuttal evidence or challenge him during deposition. Lannett also asked no questions of Dr. Klibanov despite [redacted]

[4] Lannett's argument respecting their Orange Book certification misses the point; ***Lannett*** was required to identify patents ***it*** believed "claim[] the reference listed drug." *See* 21 CFR § 314.94(a)(12). And they identified the Patents-in-Suit. Ex. 8, Smyth Op. Rep. at ¶ 28; Ex. 9, Smyth Rep. Rep. at ¶¶ 22–23.

[redacted] Ex. 10, Klibanov Dep. Tr. at 44; *see also id.* at 184 (same); 53 [redacted] Any prejudice to Lannett is of their own making.

Lannett also ignores that its own witnesses have provided testimony to establish that Zomig® is a commercial embodiment. At his deposition, Dr. Gizurarson testified as follows:

Q. [redacted]

Ex. 2, Gizurarson Dep. Tr. at 99; *see also* 96–98 [redacted] 259 [redacted] 264 [redacted] Dr. Gao also provided evidence that Summit's formulation would be [redacted]. Ex. 11, Gao Dep. Tr. at 147–149; 311 (same); *see also id.* at 170 (agreeing Summit documents [redacted] *id.* at 68 (explaining "it is the case" that [redacted] Even *if* the foregoing was not sufficient to establish nexus (and Lannett's precedent does not even suggest otherwise), Plaintiffs can adduce additional evidence on cross-examination of Lannett's witnesses.

Lannett seeks to exclude important evidence on the question of obviousness ***before*** the Court can even hear it. Apart from Lannett's arguments on the meaning of "zolmitriptan," there is no legitimate dispute that Zomig® is covered by the claims for the same reasons and evidence establishing Lannett's generic ANDA product infringes. Lannett's motion should be denied.

LANNETT'S REPLY IN SUPPORT OF ITS *IN LIMINE* REQUEST #2

Plaintiffs' reliance on Zomig NS to show secondary considerations suffers from a total lack of evidence that Zomig NS meets each and every element of the claims. Plaintiffs' reliance on *Cyclobenzaprine* is inapposite. While the Court must consider secondary considerations when presented, this does not forgive Plaintiffs' burden to demonstrate that there is a nexus.

Plaintiffs' experts fail to perform an element by element comparison of the claims to Zomig NS. Dr. Smyth's comparison of Lannett's product to the claims provides no evidence that a different product, Zomig NS, meets every claim limitation. Dr. Smyth's opinion comparing the two products is unavailing because he provides no evidence that a product considered similar under the FDA's regulatory framework would infringe the specific claim limitations. Drs. Rapoport's and Klibanov's baseless statements that Zomig NS is an embodiment of the claims cannot substitute for an element by element analysis.

Neither Dr. Gizurarson's nor Dr. Gao's deposition testimony provides a comparison of the claim elements to Zomig NS. Dr. Gizurarson's opinion that neither Zomig NS nor Lannett's product contain the claimed Zolmitriptan free base does not address other claim limitations. Plaintiffs' quote is taken out of context. Dr. Gizurarson clearly stated in the preceding testimony that he had not evaluated other claim limitations. Plaintiffs' Ex. 8, at 94:13-98:12. Dr. Gao's testimony cited by Plaintiffs also does not compare the asserted claims to Zomig NS, but rather relates only to whether Lannett's product is equivalent within unnamed regulatory guidelines.

As Plaintiffs put forth no opinion to show that Zomig NS meets each and every element of the asserted claims, there can be no nexus between Zomig NS and any secondary considerations that purportedly relate to the product. Thus, the Court should preclude Plaintiffs' experts from testifying about secondary considerations that depend upon a nexus to Zomig NS.

LANNETT'S *IN LIMINE* REQUEST NO. 3

Lannett respectfully moves to preclude Plaintiffs from presenting evidence on the plain and ordinary meaning of "suitable for intranasal administration" because Plaintiffs' experts failed to provide such opinions when appropriate, and as required, during expert discovery.

I. BACKGROUND

The Court issued an order on December 7, 2015, assigning the Court's construction to the terms "zolmitriptan;" "buffer," "buffered," and "in a buffer;" and finding that the claim preambles (e.g., "[a] pharmaceutical composition suitable for intranasal administration") are limiting. D.I. 64 at 1. In addition, the Court adopted the parties' agreed-upon construction of "disodium phosphate" and "pH of the formulation is 5." *Id.* at 2. Thus, while the preambles were determined to be limiting, the actual meaning of "suitable for intranasal administration" was not addressed during claim construction.

During expert discovery, Plaintiffs' experts failed to provide any written opinions on the meaning of "suitable for intranasal administration" even after it was clear (or should have been clear) that the meaning of the term was in dispute. When rebutting Lannett's expert's opinions, [redacted]. Reply Expert Report of Professor Alexander Klibanov ("Klibanov Report," Exh. 4 to Plaintiffs' MIL #2) at ¶¶ 49, 52. Dr. Klibanov, however, fails to provide his opinions on the term's meaning [redacted] Dr. Klibanov, for example, stated in his Report that [redacted] *Id.* at ¶ 29. Plaintiffs' other experts, Dr. Hugh D. Smyth, Ph.D. and Alan Rapoport, M.D.,

are, and have been silent on the meaning of the term "suitable for intranasal administration."

In contrast, Lannett's expert, Dr. Jinnian Gao, timely provided [redacted] Rebuttal Expert Report of Dr. Jinnian Gao ("Gao Rebuttal Report," Exh. E) at ¶ 22.

Only at his deposition did Dr. Klibanov provide his understanding that [redacted] For example, Dr. Klibanov stated that [redacted]

II. ARGUMENT

Plaintiffs should be precluded from providing expert testimony on the plain and ordinary meaning of the term "suitable or intranasal administration." Federal Rule of Civil Procedure 26(a)(2)(B) requires that a witness retained or specially employed to provide expert testimony must provide a written report which contains "a complete statement of all opinions the witness will express and the basis and reasons for them." *Honeywell Int'l, Inc. v. Universal Avionics Sys.*

Corp., 289 F. Supp. 2d 493, 500 (D. Del. 2003) (holding that testimony not disclosed in an expert's report would not be considered by the court). "As noted in the case law of this jurisdiction, the testimony of expert witnesses is limited to the information contained in their expert reports." *Id*; *see also Moore N. Am., Inc. v. Poser Business Forms, Inc.*, No. Civ.A. 97–712–SLR, 2001 WL 253117, at *7 (D. Del. Mar. 8, 2001) (precluding a party from asserting a defense where the party's expert report contained nothing on that issue); *Arthrocare Corp. v. Smith & Nephew, Inc.*, No. Civ.A. 01–504–SLR, 2003 WL 1905636, at *1 (D. Del. April 14, 2003) (excluding certain expert testimony of plaintiff because "experts are limited by their reports").

Here, Plaintiffs' experts provided no written opinions on the plain and ordinary meaning of the preamble term "suitable for intranasal administration" or any opinions on the term's construction, notwithstanding that it was Plaintiffs themselves who argued during claim construction that the preambles constitute claim limitations. Plaintiffs, therefore, should be precluded from providing such testimony at trial.

PLAINTIFFS' RESPONSE TO DEFENDANTS' *IN LIMINE* REQUEST #3

Lannett improperly seeks to preclude Plaintiffs' experts from detailing the plain and ordinary meaning of the claims' preamble because they allegedly failed to provide an opinion on this matter. As set forth below, Lannett's request lacks merit and should be denied.

Lannett correctly notes that the Court construed the preamble of the claims to be limiting, *i.e.*, "[a] pharmaceutical formulation suitable for intranasal use."[5] On this topic, Plaintiffs intend to call Drs. Alexander Klibanov and Hugh Smyth to explain the meaning of the preamble as detailed by them to Lannett throughout discovery. Initially, Plaintiffs highlight that Lannett acknowledges in its request that Dr. Klibanov stated he would provide his opinions on "the characteristics of a suitable formulation" and "the correct physicochemical makeup of the formulation to render it suitable for use." As such, Lannett was on notice to probe—and did probe—Dr. Klibanov's opinion during deposition. Indeed, the majority of his deposition centered on the meaning of the preamble. Moreover, Drs. Klibanov and Smyth provided much more in their expert reports and upon questioning in deposition—a fact which Lannett conveniently ignores:

- [redacted]
- [redacted]
- [redacted]

[5] Lannett focuses on only part of the preamble, i.e., the term "suitable for intranasal administration," but it is the preamble as a whole that is limiting.

[redacted]

[redacted][6]

The foregoing demonstrates that throughout Plaintiffs' experts reports and deposition testimony, Drs. Klibanov and Smyth set forth their understanding of the preamble, and Lannett was not prejudiced because it had (and indeed took) the opportunity to question Plaintiffs' witnesses on this topic.

Lannett's proffered legal support is unavailing and inapposite. In the cited *Honeywell* case, the Court excluded an expert from testifying as to the doctrine of equivalents where it was clear he *never* evaluated the issue, *never* provided any notice in his report that he would offer such an opinion, and only first opined on the issue during *direct* examination. *See Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp.*, 289 F. Supp. 2d 493, 499–500 (D. Del. 2003). The cited *Moore* case is no better; there the Court precluded the raising of an non-enablement defense where the defense was *never* raised in an expert report. *Moore N. Am., Inc. v. Poser Business*

[6] In addition, Dr. Klibanov provided still further testimony during deposition on this topic as noted by Lannett at pages 19, 56–57, 36–37, 46–47, 126–127 and 198–199 of the transcript; however, Plaintiffs disagree with Lannett's characterization of Dr. Klibanov's testimony.

Forms, Inc., No. C.A. 97-712, 2001 WL 253117, at *7 (D. Del. Mar. 8, 2001).[7] Here, Drs. Klibanov and Smyth provided notice they were relying on (and analysis of) the plain and ordinary meaning of the preamble in their expert reports, and Lannett explored this topic at their depositions showing Lannett was on notice of Plaintiffs' opinions.

Lannett's attempt to preclude Plaintiffs from providing testimony on a topic that was clearly identified in Plaintiffs' expert reports should be seen for what it is: gamesmanship. Three rounds of expert reports occurred during expert discovery, and only during the closing round (when Plaintiffs would be unable to provide a rebuttal) did Lannett introduce its unsubstantiated and plainly incorrect argument regarding the meaning of "suitable for intranasal administration."[8] Ex. 13, Gao Reb. Rep. at ¶ 22. Lannett therefore disingenuously argues Plaintiffs' experts "failed to provide any written opinions…even after it was clear (or should have been clear) that the meaning of the term was in dispute."

Plaintiffs complied with their duty of disclosure, noticed Lannett on the substance of its experts' opinions, and in turn, Lannett examined Plaintiffs' witnesses on the meaning of the preamble. Lannett's request should be denied.

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[7] The cited *Arthrocare* case is merely a court Order granting a motion *in limine* to exclude testimony but provides no underlying facts or analysis. *Arthrocare Corp. v. Smith & Newphew, Inc.,* C.A. 01-504, 2003 WL 1905636, at *1 (D. Del. April 14, 2003).

[8] As revealed at his deposition, [redacted]

LANNETT'S REPLY IN SUPPORT OF ITS *IN LIMINE* REQUEST #3

Plaintiffs' Response illustrates why their experts should be precluded from offering testimony on the meaning of "suitable for intranasal use." Despite recognizing the significance of the term, their experts provide no definite written opinion on the term's meaning. Now, in contravention of the rules, Plaintiffs state that they "intend to call" their experts "to explain the meaning of the preamble" despite that neither expert provided any such explanation in their expert reports. Rule 26(a)(2)(B) does not allow this litigation-driven subterfuge.

It is Plaintiffs, not Lannett, that are guilty of "gamesmanship."[9] Lannett's expert, Dr. Gao, provided a written opinion on the meaning of "suitable for intranasal administration." In contrast, none of Plaintiffs' expert reports provides an opinion on the meaning of the term as it is used in the claims. The only time Plaintiffs' experts address the meaning of this term in their reports is when Dr. Klibanov wrote that he may do so in the future. Klibanov Report (Ex. 4 to Plaintiffs' MIL #2) at ¶ 29. Plaintiffs' attempt to distinguish case law is unavailing. Writing that an expert may give an opinion in the future does not provide a complete statement of opinions, and "fails to even come close to satisfying the requirements for expert reports under [Rule] 26(a)(2)(B)." *Pell v. E.I. DuPont De Nemours & Co., Inc.*, 231 F.R.D. 186, 193 (D. Del. 2005).

Plaintiffs' litigation tactic to insist that the preamble is limiting, but then withhold a definition for the preamble term "suitable for intranasal administration" is a thinly-veiled attempt to hold back a basis for avoiding the prior art. Moreover, the several vague factors (including, e.g., a lack of unpleasant sensation) that Plaintiffs' expert now asserts as part of the meaning, render the term indefinite. In any event, Plaintiffs' experts failed to provide a written opinion on the meaning as used in the claims and should be precluded from providing an opinion at trial.

[9] Plaintiffs improperly place over a page of argument in single-spaced bullet points and footnotes to circumvent the Court's three-page limit on responses to motions *in limine*.